IMPLEMENTATION OF AUSDRISK SCREENING FOR TYPE 2 DIABETES IN OLDER ADULTS.

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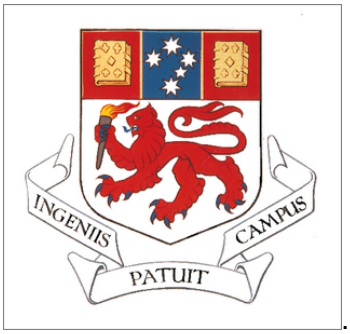

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Abbreviations

Abbreviation	Description
β-cell	ßeta cell in the pancreas produces insulin
ABS	Australian Bureau of Statistics
AGM)	Abnormal Glucose Metabolism
AHMAC	Australian Health Ministers Advisory Council
AHS	Australian Health Survey
AUSDIAB	Australian Diabetes Obesity and Lifestyle study 1999-2000. First national Diabetes, Obesity and Lifestyle Prevalence Study in Australia with over 11,000 participants aged 25+ years
AUSDIAB^{-2}	2005 Review of over 6,000 participants 5 years after AUSDIAB
AUSDRISK	Australian type 2 diabetes risk assessment tool
Biomedical assessment	Scientific assessment of blood fractions
BMI	Body Mass Index
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COACH program	Coaching for Cardiac Health and other chronic metabolic conditions
DA	Diabetes Australia, NGO for individuals with or at risk for diabetes
DBP	Diastolic Blood Pressure
DCA 2000	Machine for Point-of-Care testing
FPG	Fasting Plasma Glucose
GPs	General practitioners (medical)
HbA1c	Glycated haemoglobin
HDL	High Density Lipid blood fraction
HR	High Risk
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
Medicare	Australian Government rebate system for cost of medical procedures
mid-old	WHO definition for individuals aged between 75-84 years
MODY	Mature Onset of Diabetes of the Young
NAFLD	Non-alcoholic Fatty Liver Disease
NDSAG	National Diabetes Strategy and Advisory Group
NDSS	National Diabetes Services Scheme
NHANES	National Health and Nutrition Examination Survey

Abbreviation	Description
NHMRC	National Health and Medical Research Council
NHMRC Guidelines	Guidelines established and recommended by NHMRC
NHS	National Health Service (UK)
NSW	New South Wales (state of Australia)
OGTT	Oral Glucose Tolerance Test
old-old	WHO definition for individuals aged 85 years and over
Perceived Risk	Individual's perception of risk (subjective not objectively measured)
PHN	Primary Health Network (state-based support network for GPs)
POC	Point-of-Care testing (non-fasting)
PreDM	Prediabetes
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PubMed	US National Library of Medicine
QLD	Queensland (state of Australia)
RACGP	Royal Australian College of General Practitioners
RACGP Guidelines	Guidelines established and recommended by RACGP
RBG	Random Blood Glucose (non-fasting)
RCT	Randomised Controlled Trial
RPG	Random Plasma Glucose
SCOPUS	Elsevier's abstract and citation database launched in 2004
T1DM	Type 1 diabetes
T2DM	Type 2 diabetes
TC	Total cholesterol
TG	Triglyceride/s
VIC	Victoria (state of Australia)
WA	Western Australia (state of Australia)
young-old	WHO definition for individuals aged between 60 – 74 years

Abstract

Implementation of AUSDRISK screening for T2DM in older adults.

The research described in this thesis was undertaken in 2014–15. At that time, the World Diabetes Federation estimated there were 1.7 million Australians with diabetes (all types) which was predicted to increase to 2.3 million by 2035. A further 2 million Australians were estimated to have pre-diabetes (preDM), which doubles the risk of developing type 2 diabetes mellitus (T2DM). Type 2 diabetes is an age-related condition and life expectancy of the Australian population is increasing. Together they form the perfect storm. In 2014–15, the overall prevalence of T2DM in Australia was 4.1% with the prevalence of T2DM in the older age cohort ranging between 9.0% in the 55–64 year age group, and rising to 16.0% in the 65–74 year age group.

In Tasmania, the older age cohort is the most rapidly increasing. *Diabetes Tasmania,* the peak non-Government body representing individuals with or at risk for diabetes, reported that in calendar year 2014–15, 1,471 individuals had been newly diagnosed with T2DM in Tasmania, with 78.5% of those newly diagnosed being over 50 years and over. Of those, 22.3% were first diagnosed in their 70's, 80's and 90's. As of 30 June 2018, 29.0% of newly diagnosed T2DM were over 70 years, reflecting a dramatic increase in this older cohort.

In Australia there is no national population screening for early identification of those with, or at high risk (HR) for T2DM, and no systematic T2DM screening in primary care settings by general practitioners (GPs).

In 2010, the Australian Type 2 Diabetes Risk Assessment Tool (*AUSDRISK*) was developed to identify individuals at HR for T2DM, with recommendations for blood glucose testing to confirm glycaemic status. National Health and Medical Guidelines recommend that the *AUSDRISK* be used as the first step in a 2–3 step screening process, but the uptake is limited. In 2015, the Australian National Diabetes Strategy Advisory Group (NDSAG),

recommended a wider use of the *AUSDRISK* assessment in primary health settings, community health and non-health settings and online health services in state and federal health departments to identify individuals at high risk for T2DM.

In 2011, prior to the NDSAG recommendation, I conducted a small T2DM screening trial, and found that *AUSDRISK* could be distributed and completed via community healthcare settings. The objectives of this current study in 2014–15 were to verify the procedures and findings of the earlier study with a larger sample size of older adults, by distributing the *AUSDRISK* via 3 different community settings. The AUSDRISK was presented face-to-face in the 2 community health settings, and indirectly via a statewide mail-out specifically for older adults. The aim was to determine the feasibility, acceptability and effectiveness of using the *AUSDRISK* as the first step in T2DM screening of community-living older individuals, and to follow those at HR through to biomedical assessment.

The purpose of the study is to identify the number of older individuals at High Risk (HR) for T2DM and to determine if there were any differences in participation between a face-to-face presentation of AUSDRISK compared with receiving an AUSDRISK via mail out. The number of HR participants identified, and their baseline characteristics were established for those in each setting/recruitment method (direct/indirect). Differences in gender, age, family history of diabetes, the number and frequency of *AUSDRISK* HR score levels (HR1, HR2 HR3) were recorded and results were analysed.

The major findings of this 2014–15 study were that, although local and statewide distribution of *AUSDRISK* was feasible, older individuals did not find completion of the *AUSDRISK* to be acceptable. This lack of acceptability was associated with ignorance that older age was a risk factor for T2DM, and therefore the relevance of *AUSDRISK* was not apparent. There was no statistically significant association between the HR participants' HR score levels (HR1; HR2; HR3) and subsequently assessed glycaemic status. Of those assessed on the *AUSDRISK* as being at HR, 85.7% (42/49) were found to be normoglycaemic on biomedical assessment and 14.3% HR (7/49) were identified with Elevated Blood Glucose (EBG) frequently referred

to as preDM. The participants with EBG had scores spread across all HR levels (HR1–HR3). The average risk score of those assessed as having EBG was only 0.95 units higher (p=0.50) than those assessed as normoglycaemic.

The older age participants' knowledge of T2DM and *AUSDRISK* showed that 75.0% had never heard of the *AUSDRISK*, and 90.0% had never completed an *AUSDRISK*. Most participants were unaware of the concept of risk, as opposed to diagnosis, and considered being normoglycaemic on biomedical assessment meant they would never get T2DM.

This Real-World study demonstrated the limitations of utilizing *AUSDRISK* in T2DM screening for older age individuals. The results showed that scoring HR on the *AUSDRISK* had no significant predictive value as a first-step filter in T2DM screening in identifying those older adults who would require a confirmatory blood glucose test from those who did not. The results of this study were compared with other studies using *AUSDRISK* in a young to mid age population and with international T2DM screening studies using a greater number of biomedical assessments for older age individuals.

It is acknowledged that there may be responder bias associated with results in this ultimately small number of HR participants who completed the full screening process. However, the findings in this study were consistent with international studies using Risk Assessment Tools to identify HR for T2DM in the older age cohort.

In the light of these findings, and the importance of effective screening, consideration was given for direct implementation of a national system of regular/rolling biomedical glycaemic assessments on a 3–5 year basis for all older age individuals from age 60–74 years, along the lines of the 5-yearly UK National Health Service Health Check which includes cardiovascular and diabetes components. Implementing regular biomedical assessments would identify a pattern of increasing glycaemic results over time, and interventions, whether lifestyle and/or medication, could be implemented at an earlier stage of dysglycaemia to avert progression to T2DM.

Statement of Original Authorship

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other institution and affirms that to the best of my knowledge, the thesis contains no material previously published or written by another person, except where due reference is made in the text of this thesis.

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Date: 30 September 2019.

Statement of Authority

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Statement of Ethical Conduct

The research associated with this thesis abides by the international and Australian codes on human and animal experimentation, the guidelines by the Australian Government's Office of the Gene Technology Regulator and the rulings of the Safety, Ethics and Institutional Biosafety Committees of the University.

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To all the participants in the *AUSDRISK* study – thank you for your participation. I hope the findings from this study act as motivation for further research into screening for type 2 diabetes in older adults.

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Publications

Conference presentations

1. Population Health Congress 2015, 6 - 9 September 2015, Hobart, Australia.
2. Doctor of Health Research Seminar 22.9.2016, University of Tasmania
3. Virtual Tasmanian Academic Health Science Precinct (vTAHSP) Report 30.4.2015.

Prologue

The thesis that follows is for a Professional Doctorate completed at the University of Tasmania. The purpose of this section is to introduce myself and explain how the concept of project originated and how it was implemented. I hope that with an understanding of my background, the context of the study will be clear from the beginning.

I trained initially as a physiotherapist and practiced for many years and then worked as a manager of allied health services in a rehabilitation centre. The multidisciplinary approach to the management of acute and chronic conditions highlighted the importance of blending the psychological and physical approaches for successful health outcomes. I moved to the Population Health unit of the Tasmanian Department of Health and Human Services (DHHS) as the Diabetes Policy and Program manager which covered both state-based and national diabetes policy and project management. After several years, the area of Ageing was added to my portfolio to manage a Falls Prevention initiative for older people.

Ageing is a major non-modifiable risk factor for type 2 diabetes (T2DM), and increasing age, T2DM and sarcopaenia (loss of muscle mass and strength) are major risk factors for falls. Vascular complications (cardiovascular and cerebrovascular), lower limb sensory loss and muscle weakness associated with long-term or poorly managed or undiagnosed T2DM, are also risk factors for falls. Both T2DM and sarcopaenia impact negatively on the health and well-being of older adults.

The Australian Bureau of Statistics Australian Health Survey 2011–12 indicated that "individuals aged 60 years or older account for 70% of all persons with T2DM". Tasmania has the oldest population of all states and nationally in Australia. Registrations on the National Diabetes Services Scheme (NDSS) database in Tasmania showed that over 50.0% of patients newly diagnosed with T2DM were aged over 65 years with 17.4% in the 70–79 year age group. These figures may indicate that many older individuals are not being identified with T2DM or pre Diabetes (preDM) until well into their older years or that preDM and T2DM do not

occur until the latter years. Without a regular screening program, that would identify progression from a preDM state, diabetes is difficult to diagnose. Type 2 diabetes has a long latent period (5-10 years) when the blood glucose level is increasing but not yet in the diabetes range. There are few signs and symptoms associated with increasing blood glucose, so individuals usually are not alerted to their status of High Risk (HR) or undiagnosed T2DM.

Most individuals are diagnosed with T2DM or its precursor preDM via opportunistic screening by their GP. The usual procedure of opportunistic screening (blood test) for T2DM (every 3 years from age 45 years for those individuals at HR) via general practitioner services, was not identifying all these “mid-old” (75–84 years) to “old-old” (85 years+) individuals at an earlier age. If individuals in the earlier years of the so-called “young-old” (60–74 years) period could be identified, and if found to be at HR, provided with medication/lifestyle interventions, this management could stop/delay/reduce the impact of their HR, or undiagnosed T2DM. It could also reduce the diabetes elements in their risk for falls.

In Australia there is no national screening program for type 2 diabetes. The NHMRC Guidelines state that, although whole of population screening is not cost effective, targeted screening in High Risk groups is cost effective. If individuals were not attending their GP on a regular basis, or if GPs did not regularly screen their patients for type 2 diabetes, there would be very limited opportunity to identify those at High Risk or undiagnosed T2DM.

Internationally, and to a limited extent nationally in Australia, introduction of community-based screening programs via pharmacies, social/community groups have been used to raise awareness of T2DM and supplement the lack of systematic screening for T2DM.

The study reported in this thesis tested the feasibility, acceptability and effectiveness of implementing the *AUSDRISK* via community settings to screen adults aged 50 years and over (mean age 65.5 years) for undiagnosed T2DM or at HR.

Chapter 1. Overview

1.1 Introduction to the study

The research described in this thesis was undertaken in 2014–15 as part of the virtual Tasmanian Academic Health Science Precinct project. At that time, the International Diabetes Federation estimated there were 1.7 million Australians with diabetes (all types) which was predicted to increase to 2.3 million by 2035 (Guariguata et al., 2014, International Diabetes Federation Guideline Development Group, 2014). A further 2 million individuals were estimated to have pre-diabetes (preDM) which doubles the risk of developing type 2 diabetes (T2DM). Chronic hyperglycaemia due to undiagnosed or poorly managed T2DM increases the risk for microvascular and macrovascular complications such as blindness, kidney disease, cardiac dysfunction, stroke and amputation (Caspersen et al., 2015). The increase in T2DM was expected to be due to the increased prevalence of risk factors for T2DM, such as overweight/obesity, insufficient physical activity to gain a health benefit and the rapid ageing of the Australian population (Statistics, 2017). From 2014–15 onwards, the highest prevalence and incidence of T2DM in Australia is in the older age population – those aged 60 years and over (Australian Government Department of Health, 2016).This increase in the older age cohort with age-related chronic conditions such as T2DM is a global phenomenon (Beagley et al., 2014). In the US, Corriere et al (Corriere et al., 2013) described the developing situation as an emerging public health burden of diabetes and diabetes complications in the elderly. The overall risk for developing pre-DM/T2DM is determined by a variable combination of epigenetic, genetic, environmental and lifestyle factors (Dankner et al., 2009 ; Dankner & Roth 2015). This risk is heightened by physiological dysfunction more frequently occurring in older age – increase in insulin resistance, and decreases in pancreatic β cell function, β cell mass, and insulin secretion (De Tata, 2014, Halter et al., 2014, Imamura et al., 2013, Kalyani et al., 2013, Ling et al., 2019, Waugh et al., 2013).

Older Australians are recognised as a high-risk cohort for preDM and T2DM. In 2014–15 the older age cohort had an estimated prevalence of T2DM of between 9.0% in the 55–64 year

age group rising to 16.0% in the 65–74 year age group. The state of Tasmania has the oldest and increasingly ageing population of all Australian states/territories.

Unlike many first-world countries – for example, the United States of America (US), the United Kingdom (UK) and many European countries – Australia has no national population screening for pre-DM/T2DM, no systematic T2DM screening in General Practice and no data system nationally. The Australian National Health & Medical Research Council (NHMRC) Evidence-based Guideline for Case Detection and Diagnosis of Type 2 Diabetes (2009)(Backholer et al., 2012, Colagiuri et al., 2009a) recommends opportunistic screening via a 2-step procedure for detecting people with or at High Risk (HR) for undiagnosed T2DM – the first step is to complete a short 10-question Risk Assessment Tool (RAT) – the *AUSDRISK* – the Australian Type 2 Diabetes Risk Assessment Tool (Australian Government Department of Health and Ageing, 2008, Chen et al., 2010) to identify those at HR followed by biomedical assessments (NHMRC recommended blood test is a Fasting Blood Glucose test – FBG) to confirm their glycaemic status. The Royal Australian College of General Practitioners (Royal Australian College of General Practitioners, 2018) Guidelines for Preventive Activity in General Practice recommend following the NHMRC guidelines. However, in practice the *AUSDRISK* has not been systematically implemented by GPs (Wong et al., 2011), with most (GPs) using a patient's clinic presentation to opportunistically implement a biomedical assessment of the patient's glycaemic status, if the GP considers the patient to be at HR for T2DM.

Type 2 diabetes has an asymptomatic latent period of 5–10 years during which risk factors and blood glucose levels increase but as there are no specific signs and symptoms to identify the ongoing and progressive nature of glycaemic dysfunction pre-DM/T2DM individuals are not alerted to their increasing risk factor burden for developing pre-DM/T2DM by experiencing early symptomatology (Olafsdottir et al., 2009, Waugh et al., 2013).

Currently, the life expectancy of older individuals is greater than any previous generation and the healthcare emphasis needs to be on ensuring they retain a good quality of life, effectively

manage their health, and prevent or reduce the impact of age-related conditions such as preDM/T2DM (World Health Organisation, 2015). The WHO World Report on Ageing and Health (Beard et al., 2016a) recognises the older age group as ranging from 60 to 100+ years. Within that 30–40 year time-frame, individuals are likely to have changing health needs and therefore there is benefit in delineating 3 major "health needs" groups within the older cohort viz "young-old "(60–74 years); "mid- old" (75–85 years) and "old-old" (85+ years).

Diabetes Tasmania, the peak non-Government body representing those individuals with or at risk for diabetes in Tasmania, reported that in calendar year 2014–15, 1,471 individuals had been newly diagnosed with T2DM in Tasmania, with 78.5% in the older age group (50 years and over). Of these, 22.3% were first diagnosed with T2DM in their 70s 80s and 90s.

This finding would suggest that by implementing a T2DM screening program there is potential to identify those at HR for T2DM at an earlier age than 70 years and implement appropriate lifestyle changes and/or medication to prevent progression to T2DM.

In 2015, the National Diabetes Strategy Advisory Group (NDSAG)(Australian Government, 2015), comprising key stakeholders and the Australian Health Ministers' Advisory Council, recommended that individuals at HR for T2DM be identified using the *AUSDRISK* assessment in primary health settings, community health centres, community pharmacies, optometrists, dentists and online health services in state and federal health departments.

Implementing a T2DM community-based screening program using the *AUSDRISK* to identify older individuals at HR for T2DM, with advice to seek a confirmatory biomedical assessment, would be the first step towards effective management of their risk or to the identification of undiagnosed pre-DM/T2DM (Chamnan et al., 2012, Colagiuri et al., 2009c, Cos et al., 2015, Lee et al., 2016). This is of particular importance for the "young-old" cohort aged 60–74 years (Beard et al., 2016a) who have a potential life expectancy of a further 15–25 years and with undiagnosed glycaemic dysfunction (preDM/T2DM) would likely experience more immediate

adverse impacts and increased risk for other age-related conditions such as cancer, cardiovascular diseases, Alzheimer's Disease and frailty, with consequent reduction in their quality of life (Corriere et al., 2013, Halter et al., 2014, Kalyani et al., 2013, Wong et al., 2016).

The *AUSDRISK* has been available for self-assessment of T2DM risk since 2010 (in print and web-based), on government and non-government diabetes-related organisation sites (Australian Government Department of Health and Ageing, 2008). However, with no national T2DM screening initiative, the *AUSDRISK* has not been systematically promoted to the general public to raise awareness of risk factors (modifiable/non-modifiable) for pre-DM/T2DM nor well utilised to identify the recommended process for self-assessment of T2DM risk with follow-up biomedical assessment, if required. In 2014 the *AUSDRISK* had been used to identify HR individuals to participate in a limited number of lifestyle modification programs for T2DM prevention in a number of Australian states, including Victoria, NSW, Queensland and Western Australia, but not Tasmania (Dunbar et al., 2015, Malo et al., 2015). These programs addressed the modifiable lifestyle risk factors for T2DM – overweight/obesity; insufficient physical activity/increased sedentary behaviour; and poor/over nutrition, but increasing age was rarely mentioned as a significant risk factor for preDM/T2DM, despite its acknowledgement by NHMRC guidelines and in research (Colagiuri et al., 2009a, Halter et al., 2014, Kalyani et al., 2013, World Health Organisation, 2015).

Although the NHMRC guideline (Colagiuri et al., 2009a) does not recommend mass screening for T2DM, there is acknowledgement in this guideline that targeted screening in designated high-risk populations had been found to be cost-effective.

In 2011, as part of my role as Diabetes Policy and Program manager in the Tasmanian Department of Health, I conducted a small study implementing the Australian Diabetes Risk Assessment tool -*AUSDRISK*- to identify those at high risk for T2DM in individuals attending health services in a community health centre (public health) and 2 optometry practices

(private health). The age range of participants was 50–80 years. This study found that implementation of the *AUSDRISK* was feasible in these non-medical health settings as part of a new patient assessment. Individuals identified as HR, indicated they would attend their GP for a blood glucose test, but the study did not have the capacity to determine whether they had followed through with their intent or not.

The objectives of this study in 2014–15 sought to verify the procedures and findings of the earlier study with a larger sample size of older adults. The same non-medical health settings (as in 2011 study) were used to recruit older individuals and a statewide mail out recruitment strategy was added in an attempt to reach individuals who may not be regularly attending a GP. This study also sought to identify individual and methodological issues which may facilitate or adversely impact on older individuals participating in T2DM screening using *AUSDRISK (Colagiuri et al., 2009c).*

This study utilised a multi-method design to explore the feasibility of using community-based settings for implementing the *AUSDRISK* assessment tool as the first step in T2DM screening for individuals aged 50 years and over. For those participants identified as HR, this study wished to investigate whether they had used the Risk Score to promote them to attend their GP for a biomedical assessment (within a 5-6 week period post survey completion) and if they had attended, whether they had been diagnosed with EBG or T2DM or had a normal blood glucose level. Following this introduction chapter, the subsequent chapters reflect the background to the study: Chapter 2: Literature Review; Chapter 3: Methodology and Methods of Data collection i.e. recruitment processes and survey questionnaire; Chapter 4: provides the recruitment outcomes and analysis of participation by older adults; Chapter 5: Comprises the results and analysis of follow-up activities completed/not completed by HR participants post *AUSDRISK* completion, and the effectiveness and accuracy of *AUSDRISK* is assessed by comparison with the blood glucose test results. The chapter concludes by reviewing the comments made by older HR participants on their knowledge and acceptability of *AUSDRISK* as the initial step in identifying those at HR for T2DM; Chapter 6: Discussion

of study findings and recommendations, and Chapter 7: Policy and Future Directions for T2DM screening for older adults.

To my knowledge the *AUSDRISK* had not been used in Australia in a systematic manner as the first step in a targeted population screening procedure in a cohort of older individuals, and to follow them through to biomedical assessment. The aim of this study was to determine the feasibility and effectiveness of implementing the *AUSDRISK*, including follow-up biomedical assessment if recommended, in a real world T2DM screening scenario (Wareham et al., 2011) using community-based settings in Tasmania to initially recruit older age individuals to complete an *AUSDRISK* to assess their risk for T2DM.

1.2 Chapter 2 Literature review

This chapter presents a review of prior literature which explores the themes of this thesis. Included in these are the definitions of T2DM and preDM and an exploration of the prevalence and pathophysiology of T2DM in all ages and specifically in the older age group (aged 60 years and over). The principles and practice of screening, and how they have been progressively developed to include age-appropriate screening will be discussed, along with both the positive and negative effects of T2DM screening. International T2DM screening and prevention programs will be explored and compared with the opportunistic approach for identification and case finding of T2DM in Australia. The history of the Australian Type 2 Diabetes Risk Assessment Tool (*AUSDRISK*) and its usage to date will be examined. In addition, the adverse impact of the lack of regular/routine T2DM population screening in Australia will be reviewed.

Finally, the Australian Government health policy directives and strategies to address the increasing prevalence of Non-Communicable Chronic Diseases (NCCD)(Australian Bureau of Statistics, 2013) are introduced with particular emphasis on T2DM, including recommendations to increase use of *AUSDRISK* to identify those at risk for T2DM.

1.3 Chapter 3 Methodology and methods

Chapter 3 provides the philosophical viewpoint, theoretical underpinning, ethical considerations and rationale for the methods utilised in this research project. The methods for the Literature Review and the *AUSDRISK* project will be presented in detail. The choice of the multiple method approach in this research was determined by aiming to achieve a comprehensive pragmatic approach (complementarity, completeness, development, expansion and confirmation) in relation to implementing the Type 2 Diabetes Risk Assessment Tool – *AUSDRISK* – for community-based screening to identify older age individuals with (undiagnosed) or at high risk for developing Type 2 Diabetes (T2DM).

The multiple methods framework for this study implements a process similar to that designed for mixed methods with the following steps – *Exploratory Sequential* at the design level, then via *multi-stage* inputs from each of the recruitment settings. Quantitative analysis of the first stage allows for identification of the number of those older age participants who scored High Risk on the *AUSDRISK*. After completion of the *AUSDRISK* the participants who scored HR were invited to voluntarily provide details on their follow-up actions to attend/not attend their GP. This information was gathered in Phase 2 and served to *form/build* the next database which expanded on the quantitative data collected in Phase 1.

In addition, HR participants in Phase 2 were invited to provide their knowledge and experiences (beliefs and attitudes) towards screening for T2DM risk using the *AUSDRISK* as the first step in the screening process. The quantitative data and qualitative data were then considered separately and in combination.

1.4 Chapter 4 Methods of data collection and analysis (phase 1)

The study aimed to replicate a real-life T2DM screening initiative for older individuals in community settings in which they were advised the importance of knowing their risk for T2DM and inviting them to complete an AUSDRISK risk assessment. Those who scored HR were advised that scoring HR was not a diagnosis of T2DM, but that they were advised to

follow the instructions on the AUSDRISK and attend their GP to have a blood glucose test. This chapter describes Phase 1 (quantitative elements) of the multi-method study which included the number of AUSDRISK risk assessment tests distributed in three different community settings (2 health-related settings and a statewide mail out), and the number of the *AUSDRISK* completed by older adults residing in the community. The purpose of this phase of the study was to identify the number of older individuals at High Risk (HR) for T2DM, to determine if there were any differences in participation between a face-to-face presentation of AUSDRISK compared with receiving an AUSDRISK via mail out. During this phase of the study the number of HR participants and their baseline characteristics were established for those in each setting/recruitment method (direct/indirect). Differences in gender, age, family history, the number and frequency of *AUSDRISK* HR score levels (HR1, HR2 HR3) were recorded and results were analysed.

1.5 Chapter 5 Results of high risk participants' follow-up survey and effectiveness of the AUSDRISK

This chapter covers the qualitative components of the study – the results of those participants identified by their *AUSDRISK* score as being at HR, who subsequently completed the follow-up survey reporting on the reasons they provided for attending or not attending their GP; the GPs' response to those HR participants who attended their GP following completion of an *AUSDRISK*; the glycaemic status of those HR participants who had a blood test; and HR participants comments on their experience of completing an *AUSDRISK*.

1.6 Chapter 6 Discussion and findings

This chapter synthesises the findings of the study sequentially from initial distribution of *AUSDRISK* to older age adults, to participation/non-participation in the full screening process. The results are interpreted in relation to *AUSDRISK* presentation and scoring and in relation to the older age participants' capacity to self-assess their risk for T2DM. The overall

significance of the findings is discussed with reference to the use of *AUSDRISK* in different age-range cohorts and with reference to other screening to prevention initiatives in Australia and other T2DM screening strategies internationally.

1.7 Chapter 7 Conclusions, recommendations and future directions

This chapter reviews the major findings of this research and considers them in the light of proposals and initiatives subsequent to completion of my research, for T2DM screening in Australia, generally and particularly for older individuals. As with many health-related initiatives, progress to achieve T2DM screening has been slow. The reasons for this will be discussed and compared with screening and management initiatives, such as the systematic approach of *NHS Health Check* and personalised medicine approach for diagnosis and management of T2DM advocated by international researchers.

Since 2015, there has been a large volume of research which has prompted major changes in considering the pathology of T2DM from it being a lifestyle disease to it being a complex heterogeneous condition involving epigenetic, genetic, ageing and environmental factors. This chapter covers the T2DM initiatives and issues (government and non-government) considered in Australia since this research in 2014–15. These initiatives include:

1. The commencement of a Medicare funded annual diagnostic HbA1c test for asymptomatic individuals considered to be at HR by their GPs.

2. The impact of current situation with reference to an ongoing lack of a national system for T2DM prevention and screening in Australia.

3. The most recent 2017–18 Australian Health Survey (Australian Bureau of Statistics, 2018) – diabetes (all types) and T2DM results which show little change in the prevalence of T2DM and age of T2DM diagnosis since 2015. Whilst there has been virtually no change in T2DM incidence overall there has been a significant increase newly diagnosed older individuals aged 70 years and over.

4. The potential impact of Australia's My Health Record system – as from December 2018, all Australians will be recorded on the digital My Health record system but be able to "opt out" should they wish. Current issues – individual privacy; benefits of access to GPs, hospitals, other health professionals.

5. Rationale for and consideration of a Diabetes/CVD health check for "young-old" individuals from age 60–74 years or (50–70 years) along the lines of the *National Health Service (NHS) Health Check program* in the UK (Martin et al., 2018, Robson et al., 2016, Usher-Smith et al., 2017) will be presented.

6. Rationale for the move away from identifying established T2DM, towards the identification and treatment of prediabetes (with lifestyle intervention and/or medication). This approach is now considered as being essential for achieving T2DM prevention in US, UK and many European countries (Apolzan et al., 2019).

Chapter 2. Literature review

2.1 Introduction

In the 7th International Diabetes Federation Diabetes Atlas 2015 the following prediction was made:

> *The prevalence of diabetes (all types) worldwide is estimated to be 415 million adults aged 20–79 years, including 193 million adults who are undiagnosed. A further 318 million adults are estimated to have impaired glucose tolerance, which puts them at high risk of developing the disease. By the end of this year (2015), diabetes will have caused 5.0 million deaths and have cost between USD673 billion and USD1, 197 billion in healthcare spending. If this rise is not halted, by 2040 there will be 642 million people living with the disease.(International Diabetes Federation Diabetes Atlas Committee, 2015).*

The prevalence of diagnosed diabetes and HR for diabetes, along with the associated costs for healthcare management in Australia, follow a similar pattern to that observed worldwide. The prevalence of diabetes (all types) is expected to increase to 2.3 million people by 2035 (Guariguata et al., 2014, International Diabetes Federation Diabetes Atlas Committee, 2015).

The results from the most recent completed Australian Health Survey (AHS) 2011–12: Biomedical Results for Chronic Diseases (Australian Bureau of Statistics, 2011-12) showed 1.2 million (5.1%) Australians aged 18 years and over had diabetes, comprising 4.2% with known diabetes and 0.9% with diabetes newly diagnosed from their results of a fasting plasma glucose test.

Thus, there was approximately one newly diagnosed case of diabetes for every four diagnosed cases. In addition, 3.1% of adults had IFG, placing them at high risk for developing diabetes. Thus, for every four persons diagnosed with diabetes, there were an additional three people at high risk for diabetes.

Diabetes was more common among men than women in 2011–12 (6.3% men compared with 3.9% women). This was the case for both diagnosed diabetes (4.9% compared with 3.4%) and newly diagnosed diabetes (1.4% compared with 0.4%).

There are two main types of diabetes – Type 1 and Type 2 (Diabetes Australia, 2017a).

Type 1 diabetes (T1DM) (approximately 8-9% total diabetes) is an autoimmune condition causing rapid loss of beta cell function in the pancreas with consequent loss of insulin requiring lifelong insulin replacement. Type 1 diabetes is predominantly a disease of young persons. Type 2 diabetes (T2DM) (approximately 85–88% total diabetes) is affected by both genetic and environmental factors with a gradual increase in blood glucose levels over a period of 5 to 10 years. In 2017, Chattterjee et al (Chatterjee et al., 2017) described this relationship as genetic factors exerting their effect following exposure to an obesogenic environment characterised by sedentary behaviour and energy dense diets.

The prevalence of T2DM increases with advancing age. People aged 65–74 years had the highest rate (15.0%) of T2DM. People aged between 55–74 years had the highest rates of newly diagnosed T2DM (2.3%). The proportion of people at HR for T2DM also steadily increased with the highest “HR” group being those aged 75 years and over (7.5%)(Australian Bureau of Statistics, 2011-12, Diabetes Australia, 2017b).

The 2011–12 AHS Biomedical Results for Chronic Disease (Australian Bureau of Statistics, 2013) also showed that people who were obese had much higher rates of diabetes (11.2%) than those who were overweight (4.1%) or normal or underweight (1.6%). Similarly, for individuals assessed as being at HR, those who were obese had the highest risk (5.8%) for developing T2DM, compared of those of normal weight or underweight whose risk was 0.9%.

Individuals with a family history of diabetes were also more likely to have, or be at high risk for, diabetes. Results (Australian Bureau of Statistics, 2011-12) showed that 54.4% of those with diabetes and 39.9% of those at high risk, had a close family member who had the condition. However, research by Aujla et al 2013; Lavielle et al 2014, had shown those with a Family History have an ambivalent attitude to confirming, or not, their diabetes status. This was due to the individuals' perception of threat and feelings of vulnerability to the development of T2DM, which was influenced by the individuals' environment and previous experience with diabetes.

Diabetes (all types) is also a major risk factor for cardiovascular disease. Individuals with diabetes were twice as likely as those without, to have abnormal (low) levels of beneficial HDL (48.6% compared to 21.7% without diabetes) and higher levels of triglycerides. Those individuals with elevated blood glucose which places them at high risk for developing type 2 diabetes also show abnormal levels of HDL and triglycerides.

The Australian National Health Survey (NHS): First Results, 2014–15 ((Australian Bureau of Statistics, 2015b) released December 2015) showed that in Tasmania the levels of diabetes was similar to the national percentage of DM at 5.1% but the risks for type 2 diabetes were higher than in most other states/territories and nationally. Tasmania had the highest levels of heart disease (National 5.2%;Tasmania 7.7%), high cholesterol (National 7.1%: Tasmania 9.4%), hypertension (National 11.3%: Tasmania 16.4%) and kidney disease (National 0.9%: Tasmania 1.5%) . It was acknowledged that these high levels may be in part be due to the fact that Tasmania has the oldest population of any Australian jurisdiction. However, Tasmania also has the highest proportion (state/territory and nationally) of men and women aged 18 years and over who are overweight or obese (male 74.1%; female 60.9%; Total 67.5%) as compared to nationally (70.8%; 56.3%; 63.4%). Furthermore, individuals in Tasmania reported the lowest levels of physical activity sufficient for a health benefit in Australia (for both men (44.3%) and women (42.0%) in comparison to the national average of 47.7%)(Australian Bureau of Statistics, 2015b).

Based on these findings, the Tasmanian population would be expected to have the highest risk level for developing type 2 diabetes/prediabetes, and the lowest level of protective factors (sufficient physical activity for a health benefit, normal weight) in both modifiable factors (lifestyle, body weight and physical activity) and non-modifiable factors (age) of all Australian jurisdictions.

Since the completion of my research there have been two National Health Surveys conducted and reported by the Australian Bureau of Statistics (ABS) - in 2014-15 and the most recent in 2017-18 which was reported in 2019.

The 2017-18 National Health Survey was designed to collect a range of information about the health of Australians, including:

- prevalence of long-term health conditions;
- health risk factors such as smoking, overweight and obesity, alcohol consumption and physical activity; and
- demographic and socioeconomic characteristics.

The survey was conducted in all states and territories and across urban, rural and remote areas of Australia (excluding very remote areas) from July 2017 to June 2018. The survey included around 21,000 people in over 16,000 private dwellings.
In 2017-18, one in twenty Australians (4.9% or 1.2 million people) had diabetes. Since 2001, this rate has increased from 3.3%, however, has remained relatively stable since 2014-15 (5.1%).
Diabetes continued to be more common among males than females (5.5% and 4.3% respectively). The prevalence of diabetes has increased for both males and females since 2001 (both 3.3%).

As found with many chronic health conditions, the rate of diabetes increased with age. Since 2001, the rate of diabetes has remained fairly consistent up to age 64 years whilst older

adults have experienced increases. The rate of diabetes amongst adults aged 65-74 year olds increased from 12.5% in 2001 to 15.4% in 2017-18. Meanwhile, of adults aged 75 years and over, almost one in five (18.7%) had diabetes in 2017-18; which was an increase from 11.2% in 2001.

Since 2001, the rate of diabetes amongst men aged 65-74 years increased from 11.8% to 18.7% and for those aged 75 years and over from 11.2% to 20.7%. Similarly, the rate of diabetes amongst women has increased for those aged 75 years and over from 11.2% in 2001 to 17.0% in 2017-18.

2.2 Background

2.2.1 Australian Government health policy

In response to the increasing prevalence of diabetes, the Australian Government released the *Strategic Framework for Action – Advice to Government* on development of the *Australian National Diabetes Strategy* 2016–2020 (Group, 2015) with aims and directives to prioritise Australia's response to diabetes (all types) and identify approaches and action areas to reduce the impact of diabetes in the community by effective prevention, detection and management of diabetes (all types).

In 2015, the National Diabetes Strategy Advisory Group (Australian Government, 2015) provided expert policy advice on diabetes prevention and care, in consultation with key stakeholders and the Australian Health Ministers' Advisory Council. The NDSAG defined 7 high-level Goals for the Australian National Diabetes Strategy 2016–2020. The first two goals addressed prevention and earlier detection of individuals with or at high risk of type 1 or type 2 diabetes.

Goal 1 addressed issues to reduce the number of people developing type 2 diabetes – taking a whole-of-population approach to encourage and enable healthier lifestyles.

Goal 2 was aimed at promoting earlier detection of type 1 and type 2 diabetes – to facilitate earlier diagnosis and earlier treatment for all forms of diabetes. In relation to earlier detection of type 2 diabetes the following initiatives were recommended:

- Establish a nationally coordinated detection program to identify high-risk individuals using the *AUSDRISK* screening tool
- Establish multiple avenues for the dissemination of *AUSDRISK*, using Primary health networks, community health centres, community pharmacies, optometrists, dentists and online health services in state and federal health departments
- Promote increased use of the *AUSDRISK* screening tool among all age groups – with the acknowledgement that this may require calibration of scoring on the *AUSDRISK* tool for different age ranges
- Integrating the *AUSDRISK* screening tool with risk assessment for other chronic conditions, including absolute cardiovascular and kidney disease risk, such as has been achieved in the UK with the National Health Service (NHS) Health Check (Robson et al., 2016) in primary care
- Improving the health literacy of the community with particular reference to risk for type 2 diabetes – both modifiable risk (lifestyle) and non-modifiable (age and genetic)
- Educating primary health care practitioners about who should be screened
- Reviewing biomedical screening methods (e.g. the use of HbA1c in the screening algorithm procedure)

2.2.2 The National Strategic Framework for Chronic Conditions 2017

The National Strategic Framework for Chronic Conditions does not replace current policies or strategies, such as the National Diabetes Strategy (NDS) 2016–2020 but provides guidance to enhance current disease-specific policies and develop new and innovative approaches to address chronic conditions. According to the council, chronic conditions are threatening to

overwhelm Australia's health budget, the capacity of health services and the health workforce (Council, 2017, Group, 2015).

In 2014–2015 more than 50 per cent of Australians reported having at least one chronic condition. Almost 1 in 3 Australians (29 per cent) aged over 65 reported having three or more chronic diseases, compared with just 2.4 per cent of those aged under 45 years. (Australian National Health Survey (NHS): First Results, 2014–15 (Australian Bureau of Statistics, 2015a, Australian Bureau of Statistics, 2015b) (released December 2015).

Priority Populations are those that are negatively impacted by chronic conditions more than the public. Not surprisingly, older Australians are considered a Priority Population. Critical life stages are critical periods throughout life where exposure to risk factors and determinants of health can independently and interactively impact on long-term health outcomes. For older individuals, retirement is a critical transition point which can be a catalyst for deteriorating health and wellbeing (Council, 2017).

Targeting opportunities to tackle chronic conditions at critical life stages, including through action to address risk factors and improve determinants of health can positively influence individual and population health outcomes (Council, 2017).

Risk factor screening for T2DM has been named as a strategic priority area, alone or in conjunction with other risk factors for cardiovascular disease as T2DM is both a disease entity and a major risk factor for developing cardiovascular disease.

2.2.3 Screening for type 2 diabetes in Australia

Currently in Australia, there is no whole of population screening for preDM/T2DM. The Australian National Health & Medical Research Council Evidence-based Guideline (NHMRC Guideline) for Case Detection and Diagnosis of Type 2 Diabetes (2009)(Colagiuri et al., 2009a, Colagiuri et al., 2009c), and the Royal Australian College of General Practitioners Guidelines for Preventive Activity in General Practice (Royal Australian College of General

Practitioners and Diabetes Australia, 2016-18) recommend opportunistic screening in general practice (Shaw, 2017) for T2DM every 3 years for adults ≥ 40 years who have risk factors for T2DM, most frequently obesity and physical activity insufficient for a health benefit, with/without family history of diabetes.

Opportunistic screening occurs when an individual attends a GP, often for a condition unrelated to diabetes, and the GP takes the opportunity to assess the individual's diabetes risk. Both the NHMRC and the RACGP guidelines are recommendations, and implementation is not mandatory. The Guidelines recommend a 2–3 step screening process for T2DM with initial completion of a risk factor questionnaire, the Australian Type 2 Diabetes Risk Assessment Tool (*AUSDRISK*) (Australian Government Department of Health and Ageing, 2008, Chen et al., 2010) to identify those at HR. Those identified as HR were advised to have a biomedical assessment (blood glucose test, since 2014, the HbA1c test has been more frequently ordered) to determine their glycaemic status whether that is normal, elevated but not in the diabetes range (PreDM), or elevated to or above the blood glucose level indicating T2DM. Further blood testing – repeat HbA1c, Fasting Blood Glucose (FBG) or Oral Glucose Tolerance Test (OGTT) – may be done if the initial result does not indicate a definitive diagnosis (Royal Australian College of General Practitioners and Diabetes Australia, 2016-18).

2.3 Australian Diabetes Obesity and Lifestyle Study (AUSDIAB) 2000

The first national Australian Diabetes Obesity and Lifestyle Study (AUSDIAB – 1) was conducted in 1999–2000, and its 5-year follow–up study in 2005 (AUSDIAB – 2) of 70 percent of the original cohort. Both studies gathered medical and lifestyle data from a stratified sample of 11,247 Australians aged 25 years and over in 42 randomly selected urban and non-urban areas of the six states of Australia (Dunstan et al., 2002b).

The Australian Type 2 Diabetes Risk Assessment Tool (*AUSDRISK*), based on the findings of the AUSDIAB and AUSDIAB–2 studies, was developed in 2008 as a screening tool to

identify those at High Risk (HR) for developing T2DM (Chen et al., 2010). The *AUSDRISK* has been validated as a predictor of diabetes risk at 5-year follow-up and has been acknowledged internationally as a valid and reliable pre-screening test to identify people at HR for developing T2DM (Noble et al., 2011).

The Australian *National Evidence Based Guideline for the Primary Prevention of Type 2 Diabetes* (Colagiuri et al., 2009b) notes that:

> *Using an AUSDRISK score of ≥ 15 has a sensitivity of 54.3%, specificity of 83.1% and a PPV of 16.9% for predicting development of T2DM over the next five years. An AUSDRISK score of ≥ 15 identifies approximately 15% of the total population at HR for developing T2DM within five years.*

Chen et al (Chen et al., 2010) reported that the area under the receiver operating curve (AROC) of the *AUSDRISK* tool was 0.78 (95% CI, 0.76–0.81) and the Hosmer-Lemeshow goodness of fit test for logistic regression (HL) $\chi 2$ statistic was 4.1 (P=0.85). Using a score ≥12 (maximum, 35), (the point at which the sensitivity and specificity were maximised) the sensitivity, specificity and positive predictive value for identifying incident diabetes were 74.0%, 67.7% and 12.7%, respectively. Australian diabetes prevention programs needing to account for cost and feasibility of the program have chosen a threshold of ≥ *15* as the entry point for participation. The *AUSDRISK* performance was assessed by applying it to other Australian cohorts. In relation to discriminative ability the *AUSDRISK* and was found to have performed moderately in the Blue Mountains Eye Study (BMES) of an older age population (Cugati et al., 2007) whereas the discrimination was good in the North West Adelaide Health Study (Colagiuri et al., 2009b) with a wider age range. It was noted that "the weighting of the age categories is likely to be smaller when a score derived from a wider age group is applied to a population with limited age range". It was noted that the *AUSDRISK* calibrated well in the BMES cohort (HL $\chi 2$ statistic, 9.2; *P*=0.32). However it had less discrimination in predicting incident diabetes with an AROC of 0.66 (95% CI 0.60–0.71) lower than in the original AusDiab cohort (AROC of 0.75 (0.72–0.78) (Chen et al., 2010).

2.4 Type 2 Diabetes Risk Assessment tool (AUSDRISK)

At the time of my research the *AUSDRISK* was only available as a paper-based screening tool. It has subsequently been made available on the Australian Government health website (https://www1.health.gov.au/internet/main/publishing.nsf/Content/diabetesRiskAssessmentTool)

Risk factors (modifiable and non-modifiable) for T2DM are each given a weighted numeric value and the total of the Risk Factor points provides an estimate of the risk for an individual's development of T2DM over a 5–7 year period. The risk factors included in the *AUSDRISK* are very similar if not the same as nominated risk factors in the NHMRC Guidelines for Case Detection and Diagnosis of T2DM (Colagiuri et al., 2009c) and the RACGP Guidelines for Preventive Activities (Royal Australian College of General Practitioners, 2018). An algorithm is used (based on results from the AusDIab –1 and AusDiab –2 studies) to weight the risk factors individually and in combination that makes the *AUSDRISK* an effective screening tool for identifying risk for T2DM in the Australian adult population. The quantified total risk levels are designated Low risk (5 points or less), Intermediate risk (6–11 points) and High risk (12 points or more). On the more recent on-line version of AUSDRISK there have been some minor changes in the recommendations associated with particular scores - Low risk (5 points or less); Moderate risk (6 – 8; 9 – 11); High risk (12-15; 16-19); Very High risk (20+). Individuals scoring HR would be advised to attend their General Practitioner for a biomedical assessment of their diabetes status. Although use of the *AUSDRISK* is recommended as the first step for T2DM screening, it has not been systematically used for individual screening by GPs, who prefer to use direct biomedical assessment as the first step (Shaw 2017; Lee et al 2016). The *AUSDRISK* has never been used for whole-of-population screening.

In a 2015 editorial, Colagiuri (Colagiuri, 2015) predicted that in future screening protocols may begin with completion of a non-invasive risk assessment tool, followed by HbA1c testing in the high-risk group to detect undiagnosed diabetes, and high-risk non-diabetic individuals. Those identified as with or at very high risk of diabetes would then be referred to lifestyle

modification-based diabetes prevention programs. However, this prediction is yet to eventuate and the *AUSDRISK* has been mainly utilised in Australian states and territories for self-assessment during diabetes health promotion events to raise awareness of risk for T2DM. It has also been used to provide the criteria (score) for inclusion of HR participants in a number of diabetes "screen and treat" prevention programs for individuals aged 40–49 years in some Australian states but not Tasmania (Dunbar, 2017, Dunbar et al., 2015, Malo et al., 2015, Vita et al., 2016).

2.5 Population ageing

The cohort of older adults is the fastest growing section of the Australian population. The Australian Bureau of Statistics, Census on Population and Housing (Australian Bureau of Statistics, 2015a) reported there were 3.7 million (15%) Australians aged 65 years and over – increasing from 319,000 (5%) in 1926 and 1.3 million (9%) in 1976. By 2056, it is projected there will be 8.7 million older Australians (22% of the population) and 12.8 million (25%) by 2096 (Australian Bureau of Statistics, 2015a).

Currently Tasmania has the highest proportion (18.0%) of persons aged 65 years and over of any Australian jurisdiction. i.e. almost one in five of the population (Australian Bureau of Statistics, 2015a).

Life expectancy of older individuals is longer than in any previous generation. The increasing proportion of older Australians is due partly to the increasing life expectancy of older adults. For example, in 2011–13, a 65-year-old man could expect to live another 19 years and a 65-year-old woman, another 22 years – 7 years longer for both sexes than in the mid-1960s. To best respond to the increased requirements of this larger aged population, the health system needs to understand and address the most common health conditions experienced by older Australians.

The *World Report on Ageing and Health* (Beard et al., 2016b) recognised the older age cohort as ranging from 60 to 100+ years. Within that 30–40-year time frame, individuals are

likely to have changing health priorities. Therefore, there is benefit in delineating 3 major "health needs" groups within the older cohort viz "young-old" (60–74 years); "mid- old" (75–85 years) and "old-old" (85+ years).

At the time of conducting this research the results of the 2011–12 Australian Health Survey (Australian Bureau of Statistics, 2011-12) showed the most commonly reported chronic condition (excluding short- and long-sightedness) was arthritis, affecting half of people aged 65 years and over. Other conditions that had higher prevalence rates in older Australians included vascular diseases (Ischaemic Heart Disease, Cerebrovascular disease and dementia), T2DM; and osteoporosis. Whilst each condition is reported separately, they frequently occur as comorbidities or confounders adversely impacting on the overall health and wellbeing of older individuals. In order to achieve effective management of these multiple and interacting chronic conditions, there is increased demand for, and on, primary care medical and allied health services.

The AHS 2011-12 results reported the prevalence of diabetes in the older age cohort increased from 4.0% for the general Australian population to approximately 9.0% in the 55–64-year cohort and increased further to 16.0% in the 65–74-year cohort – the highest rate of diabetes recorded in the AHS 2011-12 results.

In 2011-12, 4.0% of the Australian population (875,400 people) reported having some type of diabetes (excluding persons with gestational diabetes). The prevalence of diabetes remained stable between 2007-08 and 2011-12 (both 4.0%).

Of persons who reported diabetes, the majority had Type 2 diabetes (85.3%), while 12.4% had Type 1 diabetes and the remainder had an unspecified type of diabetes (2.3%).

More men reported having diabetes than women (4.3% of all men compared with 3.6% of all women) and as with many health conditions, the rate of diabetes increased with age.

The National Diabetes Services Scheme (NDSS) dataset of individuals with diagnosed diabetes (all forms) (Australian Government Department of Health, 2016) records individuals in their late 60's 70's and 80's as being newly diagnosed with T2DM. It is unknown how

many in the older age group have remained undiagnosed with T2DM over many years, or whether those individuals diagnosed with T2DM in their older years have had increasing levels of hyperglycaemia, which finally reached the level for a diagnosis of T2DM.

Prolonged hyperglycaemia, whether due to prolonged preDM, undiagnosed T2DM or diagnosed T2DM with poorly controlled glycaemic status, causes significant increased risk for cardio-metabolic conditions (macro- and microvascular complications – heart attack, stroke, nephropathy, retinopathy), cancers, vertebral fragility and fractures (Sanches et al., 2017), falls and dementia (vascular and Alzheimer's disease). T2DM is associated with significant increased risk for disability, compared to people without T2DM (Koye et al., 2017, Schneider et al., 2016, Schneider et al., 2013, Wong et al., 2016). Australian research by Wong et al (Wong et al., 2016) showed people with T2DM had 50.0%–80.0% increased risk of disability and hospitalisations compared to those without T2DM. As the number of older people living in Australia continues to increase, optimizing their health and wellbeing (Schneider et al., 2016) (Beard et al., 2016b) is an increasingly important economic and medical necessity, and challenge for society.

Since completion of this research, the Australian Health Survey 2017-18 reported that whilst the rate of diabetes has remained steady for adults up to age 64 years, there has been an increase in the 65-74 year group from 15.0% to 15.4% and for those in the 75+ group the rate has reached 18.7%.

2.6 T2DM screening for older individuals in Australia

As there is no systematic national screening for T2DM and preDM, the prevalence of risk for T2DM in older adults, that is elevated blood glucose (EBG)/preDM, is unknown due to lack of national recording. Estimates of the prevalence of abnormal glycaemia from the US and UK (Twito et al., 2015) state the prevalence of preDM to be close to 50% in older adults.

Although the NHMRC Guideline for Case Detection and Diagnosis of Type 2 Diabetes (Colagiuri et al., 2009c) does not recommend mass/whole of population screening for T2DM,

there is acknowledgement that targeted screening in designated high-risk populations has been found to be cost-effective. (Colagiuri, 2012, Lee et al., 2013).

In Australia, adults with or at high risk for T2DM are most frequently identified by their General Practitioners. The guidelines for preventive activities in general practice recommend that adults >40 years of age and being overweight or obese, and/or with an AUSDRISK score of 12 points or more, should be screened by having an HbA1c test or FPG test every 3 years. However, there is no national funded or independently managed program to support this, unlike for example, with breast and colon cancer screening. Patients with or at HR for T2DM are identified when they attend a GP for a matter relating or not to T2DM risk, and the GP takes the opportunity to implement a blood test – so-called “opportunistic screening”.

Implementing a national T2DM risk-screening program in Australia to identify elevated blood glucose levels in “young-old” individuals, age 60–74 years, would be the first step towards improving awareness of preDM/T2DM and facilitate effective management of older individuals’ level of risk for, or presence of, undiagnosed pre-DM/T2DM (Caspersen et al., 2015, Chamnan et al., 2012, Cos et al., 2015, Lee et al., 2016). Ideally such a program would commence by identifying the glycaemic status of older individuals aged 60–65 years. Those identified as having preDM or T2DM would be advised to commence lifestyle modification and/or medical management. Currently the *guidelines for preventive activities in general practice* recommend that those individuals at HR, but not yet meeting the diagnostic criteria for preDM or T2DM conditions, should receive lifestyle advice and be reviewed in one to three years by their general practitioner. However, the lack of a national - funded initiative to support these recommendations also impedes the consistent implementation of these recommendations.

The following literature review will address the issues pertinent to T2DM screening in older adults.

2.7 Literature search methodology

2.7.1 Methods

A detailed literature search, nationally and internationally, was undertaken to review the rationale, risk assessment procedures, the facilitators, and barriers to the uptake of health screening for older individuals, with particular emphasis on T2DM and its precursors preDM/non-diabetic hyperglycaemia.

2.7.2 Search strategy

The online databases PubMed, CINAHL, and SCOPUS were searched using the following terms: Diabetes Mellitus, type 2: prediabetic state: hyperglycaemia AND risk factors: precipitating factors AND asymptomatic: undiagnosed AND surveys and questionnaires: health status indicators: risk assessment: screening; risk assessment tool AND aged: older adults: people over 60 years: young-old: seniors.

The starting point of 1990 was chosen to cover T2DM screening prior to the use of Risk Assessment Tools.

Additional searches comprised follow-on references in articles already in hand, and from government, non-government sources and policy documents relating to prevention and management of type 2 diabetes.

The search retrieved information for 1235 articles. After title scanning 671 articles were selected as potentially relevant. Abstracts were reviewed with 639 being relevant for a full review. Additionally, papers were identified through ancestral searches of bibliographies and cited research articles.

2.7.3 Inclusion/exclusion criteria

Articles included related to one of the following topics:

- Type 2 diabetes and prediabetes

    - Pathophysiology – all ages; specifically, in the older age group
    - Prevalence – all ages; specifically, in the older age group
    - Complications and increased risk for other medical conditions
- Screening Guidelines and policies
- Screening interventions
    - Screening via medical practitioners
    - Screening via other health practitioners
    - Non-medical/non-health screening interventions
    - Screening type – opportunistic, targeted, population
    - Screening – specifically older age cohort
- Risk Assessment
    - Risk assessment tool prior to biomedical assessment
    - Assessment of known risks – biomedical
- Qualitative impacts on participation and outcome of screening
    - Socioeconomic
    - Perception of diabetes risk
    - Diabetes awareness, Health literacy
- Economic
    - Cost of screening
    - Cost of type 2 diabetes/prediabetes

- Articles excluded:
    - Non-English language
    - Any papers with risk assessment not covering 60–74-year age range
    - Any papers with participant mean age less than 65 years
    - Type 1 diabetes, Gestational Diabetes Mellitus, LADA
    - Genetic factors only

2.7.4 Article selection

The titles and key words section of the articles identified by the searches were examined and those which were not on the topic for consideration were excluded. The abstracts of the remaining articles based on the major inclusion criteria were read again; any articles, which appeared potentially relevant were kept for further examination. The process was reviewed and accepted by 2 of my earlier supervisors who for various reasons moved on. The work was part of my confirmation. The search strategy followed a systematic process using the PRISMA as a guide but was not a systematic review.

The remaining articles were then examined fully (the whole text) for the specific topic relevance for which they would be used.

The following literature review critically reviews and discusses the literature identified, first to situate the range of elements involved in T2DM and preDM screening; ageing and increasing longevity and the impact of both elements on the community and society. Key findings and their possible implications are then summarised and discussed.

2.8 What are type 2 diabetes (T2DM) and prediabetes?

"Approximately 85 per cent of people with diabetes have type 2 diabetes which is both a disease entity and a risk factor for other diseases, predominantly cardiovascular and cerebrovascular disease." (Colagiuri et al (2009c))

Diabetes is not a single homogeneous disease but composed of many conditions with hyperglycaemia as a common feature. Leslie et al (Leslie et al., 2017, Leslie et al., 2016) notes that four factors have historically been utilised to describe this diversity namely: age of onset; the severity of the disease (i.e. the degree of loss of β cell function); the degree of insulin resistance, and the presence of diabetes-associated autoantibodies. Based on these factors there are two major types – type 1 diabetes mellitus and type 2 diabetes mellitus. However recent and ongoing research has found that both major types of diabetes have common features. Type 1 diabetes is a so-called *exclusive* disease in that the term

encompasses individuals with diabetes-associated autoantibodies, who are dependent on exogenous insulin. Whereas T2DM, is an *inclusive* disease. It has a complex aetiology that cannot be defined by a single feature. In fact, T2DM broadly covers any form of diabetes that is not T1DM, MODY (maturity onset of the young) or secondary diabetes (Leslie et al., 2017, Leslie et al., 2016).

2.9 Pathophysiology of type 2 diabetes (T2DM)

Normal regulation of glucose metabolism is determined by a complex feedback loop involving dietary intake, the islet β-cell, counter-regulatory hormones (including adrenaline and noradrenaline, glucagon, cortisol and growth hormone) and insulin-sensitive tissues. The β-cells are located in the pancreas as one of at least five different types of islet cells in the islets of Langerhans. They produce, store and release the hormone insulin. (Diabetes UK 2019)

In normal situations, insulin acts to drive down the blood glucose level, which has risen in response to diet or other metabolic needs (e.g. stress). When tissues become resistant to the effects of insulin (as occurs in PreDM and T2DM) the β-cell responds, in the initial phase, by producing more insulin. It is only when the β-cell, is incapable of releasing sufficient insulin in the presence of insulin resistance that glucose levels rise (Kahn et al 2014). Hyperglycaemia develops in type 2 diabetesT2DM when there is an imbalance of glucose production and glucose intake (food ingestion) as opposed to insulin-stimulated glucose uptake in target tissues, mainly skeletal muscle. The influence of aging on this process is considered to be through impairment of β-cell function, resulting in a decline in insulin secretion (Lee et al., 2017). While β-cell dysfunction has a clear genetic component, complex genetic/lifestyle conditions such as obesity play a vital role (Kahn et al., 2014).

The presence of risk factors for T2DM, and increasing levels of non-diabetic glycaemia, are evident more than a decade before onset of T2DM (Olafsdottir et al., 2009). Family history, predominantly (but not exclusively) epigenetic maternal transmission, and higher Body Mass

Index (BMI), increased triglyceride (TG) and systolic blood pressure levels in late mid-life are associated with development of T2DM in later life (Feng et al., 2016, Olafsdottir et al., 2009).

Insulin resistance and β-cell dysfunction are known to be the major pathophysiologic functions driving T2DM – however these factors come into play at different time courses (Waugh et al., 2013). Insulin resistance in skeletal muscle is the earliest detectable abnormality of T2DM (Petersen KF, Dufour, Morino K et al, 2012) as quoted in (Taylor, 2013). In contrast, changes in insulin secretion determine both the onset of hyperglycaemia and the progression towards insulin therapy (Cali M, Man CD, Cobelli C et al 2009 as quoted by Taylor R 2013).

Imamura, Mukamal Meigs et al (Imamura et al., 2013) found that in older adults, the combination of risk factors causing T2DM depended on whether T2DM was preceded mainly by insulin resistance, or β-cell dysfunction or both.

Prediabetes, defined as IGT, IFG, or raised HbA1c, is not a benign state and is associated with an increased risk of cardiovascular disease/complications. The health risk is considered to be increased in people with a fasting glucose concentration as low as 5.6 mmol/L or HbA1c of 39 mmol/mol/HbA1c 6.1-6.5% (Huang et al., 2016).

In individuals with preDM, raised plasma insulin levels compensate and allow normal plasma glucose control. However, because higher insulin levels stimulate the process of lipogenesis, the scene is set for hepatic fat accumulation. Excess fat deposition in the liver is present before the onset of and during T2DM. Individual tolerance of different degrees of fat exposure varies, and understanding this lipo-susceptibility is estimated to underpin the future understanding of genetically determined risk in any given environment (Feng et al., 2016).

There is increasing interest in the role of elevated serum fasting triglycerides (Olafsdottir et al., 2009, Riediger et al., 2017) as an early sign for elevated risk for developing T2DM.

Hjellvik et al (Hjellvik et al., 2012) considered the interactions between obesity, triglycerides (TG), diastolic blood pressure (DBP) and blood glucose levels in late middle-age (50-59 years) reflected high risk for development of T2DM. Research by Dankner et al and Zou et al found T2DM was resultant from the interactions between older age, TG and non-alcoholic fatty liver disease (NAFLD) (Zou et al., 2017) (Dankner et al., 2009).

Caspersen et al (Caspersen et al., 2015) noted that between the 1999–2005 and 2006–2010 National Health and Nutrition Examination Surveys (NHANES) preDM had significantly increased for US adults aged from 50–64 years 38.5% to 45.9% *(p*=0.003) and from 65–74 years 41.3% to 47.9% *(p* = 0.016). Whilst older men had the greater prevalence of preDM, there was a significant increase in preDM for women in these two age range groups and HbA1c increased significantly for both sexes. In recognition of the increasing prevalence and impact of preDM and T2DM, screening and prevention initiatives need to target older adults, particularly in the “young-old” group (60–74 years).

2.10 Principles of screening for unrecognised high risk and undiagnosed T2DM

Type 2 diabetes is both a disease entity and a risk factor for developing, among others, cardiovascular and cerebrovascular disease (Colagiuri et al., 2009a). The precursor of T2DM – preDM is also a risk factor for the same vascular diseases. Consequently, all aspects of the impact of chronic/persistent hyperglycaemia need to be considered in evaluating recommendations for active case detection of undiagnosed T2DM. The rationale for screening in asymptomatic individuals, is to identify those with T2DM, preDM or scoring 12 points or more on the *AUSDRISK*, in association with other high risk factors such as obesity, and implement lifestyle changes and/or medication to prevent the onset, or reduce the impact of, preDM or T2DM (Colagiuri et al., 2009a, Sheehy et al., 2009).

In 1966, the World Health Organization published a monograph by Wilson and Jungner, *The Principles and Practice of Screening for Disease* (Wilson et al., 1966) (Sheehy et al., 2009).

The monograph proposed 10 principles for evaluation of screening programs which have proved to be very influential (Table 2.1). They have held up well as has been shown by evaluations performed by Andermann et al (Andermann et al., 2008), whose suggested refinements were mainly in relation to genetic counselling. In 2009, Sheehy et al (Sheehy et al., 2009) revisited Wilson & Jungner and applied the principles and practice as the basis for proposing an improved approach to screening for T2DM in the US, which would include "*risk stratification, laboratory evaluation, probability analysis and genomic testing*". In 2011, Harris et al (Harris et al., 2011), proposed that screening programs be "visualised as a balance between benefits and harms" where the net benefits to the individual and community outweigh the resources required from Health services in the public and private sectors. Harris et al (2011) considered that this balanced approach improved certainty in decision-making about implementing screening programs. Rather than using the checklist approach of Wilson and Jungner, Harris et al provided a *Summary of Steps in Evaluating Proposed Screening Programs (Harris et al., 2011),* which if followed, would provide the minimal evidence sufficient to estimate benefits and harms of screening programs with at least moderate certainty.

Within the Summary of Steps in Evaluating Proposed Screening Programs, the three main issues to be considered were:

- The probability of an adverse health outcome in the population if screening were not implemented.
- The degree to which screening identified all people who would suffer an adverse health outcome i.e. the accuracy of the screening program.
- The magnitude of the incremental health benefit of earlier versus later treatment resulting from screening.

Table 2.1 Summary of Wilson and Jungner Criteria (Sheehy et al., 2009)

Principle	Further explanation by Wilson and Jungner
The condition should be an important health problem	Does not depend on prevalence only; must consider from the point of view of the individual and community; conditions with serious consequences for either individuals or the community may both justify screening
There should be an accepted treatment for patients with recognised disease.	Perhaps most important criterion; unless there is an effective treatment, actual harm may be done; requires answering 2 questions: 1) Does treatment at the pre-symptomatic borderline stage of a disease affect its course and prognosis? 2) Does treatment of the developed clinical condition at an earlier stage than normal affect its course and prognosis? If the answer to question 1 is not clearly yes, then there is no case for screening. For question 2, effective treatment is usually ‘‘assumed.’’
Facilities for diagnosis and treatment should be available.	Must have facilities available for the diagnosis and treatment of people found positive by screening.
There should be a recognizable latent or early symptomatic stage.	Must be a reasonable asymptomatic period in the natural history of the condition.
There should be a suitable test or examination	Test must be easy and quick, may be less sensitive and specific than a diagnostic test. In a screening test, one may accept a higher false-positive rate, but a high false-negative rate would not be acceptable.
The test should be acceptable to the population.	Acceptability is related to the nature of the risk involved and the extent to which ‘‘the ground is prepared previously by health education.’’
The natural history of the condition, including development from latent to declared disease, should be adequately understood	It is necessary to have conducted enough research to know 1) What changes should be regarded as pathologic and what should be considered physiologic variations? and 2) are early pathologic changes progressive?
There should be an agreed policy on whom to treat as patients.	It is necessary to know: Is there an effective treatment that can be shown either to halt or to reverse the early pathologic changes? We must be careful to heed the Hippocratic principle of “do no harm”. There is a ‘‘borderline’’ problem whereby people are found by screening who are neither clearly normal nor abnormal. It is important to have a clear policy for either treatment or follow-up of these people.
The cost of case finding (including diagnosis) should be economically balanced in relation to possible expenditure on medical care as a whole	There are 2 general aims of screening: to improve health and to reduce costs. It is not certain that screening will reduce costs; there is a need for randomised controlled trials of screening to determine this, although these trials are difficult to conduct.
Case finding should be a continuing process and not a ‘‘once and for all’’ project.	The benefit of ‘‘single-occasion’’ screening is limited.

2.10.1 Types of screening for Type 2 diabetes

Screening in medicine is a strategy used in a population/specific population cohort to identify unrecognised disease in individuals without signs or symptoms. As such, screening tests are performed on persons in apparent good health.

Screening interventions are designed to identify disease in a community early, thus enabling earlier intervention and management, with the aim of reducing mortality and suffering from a disease. Although screening may lead to earlier diagnosis, not all screening tests have been shown to benefit the person being screened: over-diagnosis; misdiagnosis, and creating a false sense of security are some potential adverse effects of screening (Barry et al., 2017). For these reasons, a test used in a screening program must have good sensitivity, in addition to acceptable specificity.

Universal screening applies to all individuals of a certain category for example, the Guthrie heel prick blood test for all newborns in Australia to identify phenylketonuria.

Targeted screening has been implemented nationally in Australia for groups known to be at higher risk for particular conditions. For adults national screening is offered for the following conditions – bowel cancer screening commenced in 2006 (5 yearly for individuals aged 55 – 74 years) (Flitcroft et al., 2010); breast cancer screening commenced 1991 (every 2–3 years for women aged 45–74 years (and older if advised), and, somewhat more controversially, prostate cancer screening for men aged 55 -74 years commenced 1994 (Royal Australian College of General Practitioners, 2014). The national cervical cancer screening program is available for people aged 25 – 74 years. Since December 2017, the two yearly Pap test has been replaced by a five-yearly human papillomavirus (HPV) test.

In Australia, there is no national whole-of-population health screening program for T2DM as this is not considered to be cost-effective (Colagiuri et al., 2009a, Shaw, 2017) particularly when it was considered there were high levels of opportunistic screening and insufficient evidence of the benefit of introducing a national screening approach (Shaw, 2017). However

there are some researchers who consider that the current opportunistic screening approaches could be improved to identify individuals earlier to improve risk factor control once dysglycaemia is detected (Simmons et al., 2017).

Currently case finding for T2DM or preDM in Australia, involves screening individuals or smaller groups of people based on the presence of specific and/or observable risk factors, for example, overweight/obesity, limited physical activity, presence of family members having been diagnosed with T2DM or preDM. The NHMRC National Evidence Based Guideline for Case Detection and Diagnosis of Type 2 Diabetes(Colagiuri et al., 2009c) and the Evidence Based Guideline for the Primary Prevention of Type 2 Diabetes (Colagiuri et al., 2009b) recommend a 2–3 step procedure using a Risk Assessment Tool (*AUSDRISK*) as the first step to initially identify adults at High Risk for developing T2DM followed by biomedical assessment. This process is essentially 'opportunistic screening' based on observed risk factors and/or age (over 45 years), conducted by GPs. The RACGP Guidelines for Management of Type 2 Diabetes (Royal Australian College of General Practitioners and Diabetes Australia, 2016-18) are consistent with the NHMRC Guidelines. The guidelines recommend three yearly screening with an FBG or HbA1c test from 40 – 80 years for those with evidencing signs of being at HR or scoring HR on the. Those who have previously shown to be at HR by recording IGT or IFG, should be re-tested annually. However, unlike previously discussed screening programs, T2DM screening is not organised nationally and is dependent on each GP, GP practice and the attendance by individuals. It is unknown how many individuals are not identified until the later stages of experiencing dysglycaemia.

There are infrequent, short-term, local health promotion initiatives *for World Diabetes Day* or *National Diabetes Week* to raise awareness of T2DM conducted by non-Government organisations such as Diabetes Australia and its state-based branches. In addition, there have been pharmacy programs (Kilkenny et al., 2014, Krass et al., 2017, Krass et al., 2007) which have conducted screening studies utilizing *AUSDRISK*. Self-assessment via the *AUSDRISK* risk factor questionnaire may be accessed via the non-Government organisation

(NGO) *Diabetes Australia*, and by state and federal government web-sites (Australian Government Department of Health and Ageing, 2008). The *AUSDRISK* has been used to identify mid-aged adults (40 - 69 years) likely to be at HR for T2DM as the entry point for participation in time-limited lifestyle modification T2DM prevention programs (Dunbar, 2017, Johnson et al., 2015, Johnson et al., 2013, Malo et al., 2015, Vita et al., 2016) which have been conducted in other Australian states, but not in Tasmania.

2.11 Does screening for type 2 diabetes in the "young-old" age cohort, meet the principles of screening as set out by the Wilson and Jungner criteria?

2.11.1 The condition should be an important public health problem

Diabetes ranks highly on the international health agenda as a global pandemic and as a threat to human health and global economies. Over the past three decades the number of people with T2DM has doubled globally, making it one of the most important public health challenges to all nations (Chen et al., 2012). In Australia, T2DM is the fastest growing chronic condition (Australian Bureau of Statistics, 2011-12) with prevalence influenced by increased obesity and an ageing population (Australian Bureau of Statistics, 2011-12). The total prevalence of diagnosed T2DM in the Australian population is 4.4%. Results of the 2011–12 Australian Health Survey (Australian Bureau of Statistics, 2011-12) showed the prevalence of T2DM in the older age cohort increases from 4.1% in the 45-54 year cohort to approximately 9.0% in the 55–64-year cohort and rising further to 16.0–18.0% in the 65–74-year cohort. Data for 75+ cohort shows that prevalence of T2DM for males in this cohort remains at approximately 16.0% ,but for females T2DM decreases to approximately 13.0%. However, some 4-5 years later than the 2011-12 ABS findings, the National Diabetes Services Scheme (NDSS) dataset (Australian Government Department of Health, 2016) records individuals in their late 60's, 70's and 80's as being newly diagnosed with T2DM.

2.11.2 There should be an accepted treatment for patients with recognised disease

In Australia, there are national guidelines for diagnosis and treatment of T2DM. These recommended guidelines form the basis for the RACGP and Diabetes Australia guidelines for the management of Type 2 diabetes 2016-18 in primary care (Royal Australian College of General Practitioners and Diabetes Australia, 2016-18).

Within the overarching NHMRC and RACGP guidelines there is the concept of individualised treatment for T2DM, along the lines advocated by Dankner and Roth (Dankner et al., 2015) and Sinclair et al (Sinclair et al., 2015). Treatment for preDM and T2DM in older persons is 'tailored' based on person's age at diagnosis and period of abnormal glycaemic status, if known. Initial medication is usually Metformin, and some other more recent medications. Lifestyle measures include weight reduction if overweight/obese; increase in physical activity and improvement in nutrition and reduction of portion sizes, which have proved to be effective in the treatment of preDM by stabilising blood glucose levels to reduce progression to T2DM, as well as reducing complications in older adults with T2DM (Kiefer et al., 2015). This is supported by the work by Bouchard (Bouchard et al., 2012), which showed that although older adults had reduced readiness to change lifestyle measures, individualised management balancing medication and lifestyle would likely achieve desired outcomes.

Diabetes education and coaching programs, although limited, are conducted in most Australian states including Tasmania, by Credentialed Diabetes Nurse Educators (CDNE), Dietitians, podiatrists and exercise physiologists to support self-management for preDM and T2DM (Diabetes Australia, 2017b, Ski et al., 2015).

Individuals diagnosed with diabetes (all types) may access Medicare funded Care Plans (www.health.gov.au) which provide quarterly access to lifestyle interventions and quarterly blood glucose tests (FPG; HbA1c) to monitor progress.

2.11.3 Facilities for diagnosis and treatment should be available

In Australia, there are Medicare funded services available for both diagnosis and treatment for individuals with diagnosed diabetes (all types). These services are provided by the Australian network of GPs, community health services, allied health services (podiatry, psychology, dietitians, physiotherapists), pathology service, subsidised pharmacology and medications and services through the non-government Diabetes Australia and the National Diabetes Services Scheme (NDSS)(Australian Government Department of Health, 2016). Under the RACGP Guidelines for Diagnosis and Management of Type 2 Diabetes in primary care, there are medical and pathology services available for diagnosis and management (Colagiuri, 2015, D'emden et al., 2015) (Dunbar et al., 2015, Wong et al., 2011). Costs for management of T2DM such as blood glucose meters and medication are subsidised via the NDSS but are means tested. (Australian Government Department of Health, 2016).

However, there is no national system for facilitating and supporting regular screening, reporting and registration of those individuals with or at HR for undiagnosed T2DM. The Government-funded Medicare system provides one HbA1c blood test per year for diagnosing T2DM/preDM in asymptomatic adults. This may be implemented by GPs as part of opportunistic screening. There is limited treatment/management for those with preDM. *Diabetes Australia* provides information for preDM on their website and there are a small number of programs conducted by private health insurance companies for their members with ancillary service benefits. Government-funded health promotion initiatives may be utilised to increase physical activity and improve nutrition, but these are not diabetes-specific.

2.11.4 There should be a latent stage of the disease – an early asymptomatic stage exists

It has been modelled that there is a period of 5-10 years of increasing and variable glycaemic load, during which time patients are either asymptomatic, or have symptoms that do not identify the condition with sufficient precision (Olafsdottir et al., 2009).

Type 2 diabetes typically develops slowly, with progression from normal blood glucose to glucose abnormalities identified as non-diabetes hyperglycaemia or preDM and, if not treated, finally progress to T2DM. Prior to the onset of T2DM individuals may experience dysglycaemia for many years (Twito et al., 2015).

2.11.5 There should be a suitable test or examination for the condition

2.11.5.1 Diagnostic Blood tests

Diagnostic criteria for type 2 diabetes (General practice management of type 2 diabetes 2016-18)

- *Fasting blood glucose (FBG) ≥ 7.0 mmol/L or random blood glucose ≥11.1 mmol/L confirmed by a second abnormal FBG on a separate day;*
    - *FBG < 5.5 mmol/L: diabetes unlikely*
    - *FBG 5.5 – 6.9 mmol/L: may need to perform an OGTT.*
- *Oral glucose tolerance test (OGTT) before (fasting) and two hours after an oral 75 g glucose load is taken. Blood glucose is measured. Diabetes is diagnosed as FBG ≥ 7.0 mmol/L or two-hour blood glucose is ≥11.1 mmol/L*
- *Glycated haemoglobin (HbA1c) ≥ 48 mmol/mol (6.5%; on two separate occasions)*

These are via venous sampling under laboratory methodology

A random blood glucose test may be utilised but this is usually done when a person has symptoms of diabetes.

Since 2014, when the Australian Government introduced a Medicare-funded annual HbA1c test, it has become the most frequent initial test for blood glucose assessment and diagnosis of hyperglycaemia, with or without an established diagnosis of diabetes.

A Fasting Plasma Glucose (FPG) test requires an overnight fast followed by blood test and then a wait of 1–2 days for pathology testing and reporting. There are advantages in that other blood components which require fasting, (e.g. blood lipids) can be tested in addition to assessing the glycaemic status.

The Oral Glucose Tolerance Test (OGTT) – 2-hour post glucose challenge or the recent 1–hour OGTT is considered the gold standard for diagnosis of type 2 diabetes. It involves an overnight fast followed by drinking 75 ml of a glucose drink; sitting (not moving) for 2 hours (1 hour) and having blood tests every 30 mins for a 2-hour (1-hour) period. For a variety of reasons (work, family responsibilities) individuals find this process difficult in terms of time allocated for the test.

The HbA1c test, which reflects the average blood glucose levels over the previous 3 months, does not require an overnight fast and has a faster reporting time. It is convenient (it can be taken any time of day) with less day-to-day variability and international standardisation of the assay. However, the HbA1c test does not reflect the range of highs and lows of the blood glucose level nor the pattern occurring as the blood glucose returns or attempts to return to the individual's baseline level of blood glucose.

There are some limitations associated with an HbA1c test. It is not suitable for people with certain blood conditions, such as those with genetic, haematologic and illness-related factors that influence its measurement. Neither is it suitable for patients taking medication that may cause rapid glucose to rise such as steroids, and antipsychotics. The HbA1c level is reported to increase with age independently of mean glycaemia (Rothberg et al., 2015); the HbA1c test only measures blood glucose levels whereas a FPG test allows for a full blood sample analysis covering blood glucose test along with the possibility of also testing fasting lipids which if elevated reflect additional T2DM risk.

Rothberg and Halter (Rothberg et al., 2015) comment that although there may be a subset of individuals identified by either FPG or HbA1c, the identification of preDM or T2DM in the older population may need to rely on both measures, as those with an elevated HbA1c may be a different group from those with an abnormal FPG. Systematic point-of-care HbA1c testing has been found to be an effective method of initially identifying persons who are unaware of their hyperglycaemic status including T2DM and preDM (Whitley et al., 2017).

2.11.6 Risk assessment tests

The *AUSDRISK* is not a test of T2DM but rather an assessment of an individual's risk for developing T2DM over a 5-year period. If the *AUSDRISK* score is in the high range (12 points and above). Within the HR range there are 3 score levels reflecting the level of HR viz: Low HR score 12-15; Medium HR score 16-19; High HR score 20 points and above.

The score of HR (at any level) is an indicator that an individual should receive a biomedical assessment (blood test) to determine their current glycaemic status (blood glucose level). From a cost-benefit viewpoint, the *AUSDRISK* score first identifies the person/group at High Risk. This effectively reduces the number of individuals to those most likely to develop T2DM within a 5-year period. Completing an *AUSDRISK* has the added benefit of highlighting risk factors for T2DM thus improving health literacy regarding the modifiable and non-modifiable risks for T2DM. If an *AUSDRISK* is completed as a one-off event or infrequently, the HR result does not necessarily provide the incentive for individuals to attend their GP for a biomedical assessment. Regular completion of an AUSDRISK (e.g. every 2-3 years) would provide more motivation to attend their GP for a medical assessment if the individual observed their HR score was unchanged or increasing.

Many diabetes risk assessment tests have been developed worldwide since the early. Each test has been found to be most predictive if used in the population from which the test was derived (Noble et al., 2011). Each test is derived from a set of risk factors for T2DM. Different combinations of risk factors in different tools have shown to identify different levels of risk even within the same population (Gray et al., 2015), so risk tests/tools are an assessment of risk, not a diagnostic test but they do have the capacity to delineate different levels of risk for a particular condition within a target population.

2.11.7 The test should be acceptable to the population

Details have been discussed in point 2.2.3 where individual acceptability of each test was reviewed. Across the different T2DM diagnostic tests, acceptability was highest for the

HBA1c test – non-fasting and rapid reporting. However, “acceptability” also includes “perception of risk” associated with an individual’s health status. International studies have assessed and documented the impact of perceived risk for diabetes on participation with screening for T2DM and preDM and ongoing monitoring of diagnosed T2DM and preDM (Abbasi et al., 2012, Godino et al., 2014a) and found that “heightened perception of an adverse outcome” that is, a finding of T2DM or high T2DM risk, has a major negative influence on participation in screening for T2DM (Lavielle et al, 2014), and particularly for men (Davey et al., 2015). Screening appears not to be recognised by participants for its benefits i.e. early identification of potential ill-health with opportunity to reduce/avoid, but rather for its possible end-stage outcome. This may be due to the direction taken by health service providers (Mainous 3rd et al., 2019).

2.11.8 The natural history of the disease should be adequately understood

This has been covered in the pathophysiology section previously where the trajectory of T2DM if undiagnosed, is compared with trajectory of T2DM if diagnosed and managed correctly.

2.11.9 There should be an agreed policy on whom to treat

This has been addressed in the section on National Guidelines and GP management of Type 2 diabetes (2016–18).

There is recognition of the importance of a personalised approach to management of preDM and T2DM for older individuals – particularly to avoid hypoglycaemic episodes or a prolonged hyperglycaemic state (Dankner et al., 2015, Halter et al., 2014).

2.11.10 The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole

The NHMRC National Evidence Based Guideline for Case Detection and Diagnosis of Type 2 Diabetes (Colagiuri et al., 2009b) provided the rationale and evidence for identifying T2DM (benefits and cost) based on “modelling” of a national diabetes screening and prevention

program among Australians aged 45–74 years (Colagiuri et al., 2008). The Australian Diabetes Cost-Benefit Model compared baseline and scenario outcomes from 2000 to 2010. Individuals newly diagnosed with T2DM in year 2000 were “modelled” to receive intensive care which would result in reducing rates of complications. In addition, people at high risk of developing diabetes (IGT or IFG) were “offered” lifestyle intervention, reducing the numbers developing T2DM. Among those at HR, 53,000 individuals were predicted to avoid developing diabetes by 2010. Average yearly intervention and incremental treatment cost was estimated as AU$179 million, with a cost per disability-adjusted life-year (DALY) of AU$50,000.

However, the Guidelines (Colagiuri et al., 2009c) reported that in general, mass screening programs are not recommended, whereas screening for T2DM using targeted opportunistic screening in HR populations had been found to be cost effective (Borch-Johnsen et al., 2003, Wareham et al., 2001).

In 2015, Gillett et al (Gillett et al., 2015) conducted a modelling study within the NHS Health Check program to compare the cost-effectiveness of screening for T2DM using an HbA_{1c} test versus a FPG test. In addition, the study compared the use of a random capillary glucose (RCG) test versus a non-invasive risk score to prioritise individuals who should undertake an HbA_{1c} or FPG test. The study utilised results from the multiethnic population currently attending NHS Health Checks. According to Gillett et al (Gillett et al., 2015) it was more cost-effective to screen for T2DM using a HbA_{1c} test than using a FPG test. Use of a Risk Assessment Test was considered to be more cost-effective than a random plasma glucose test for pre-screening to determine those at high risk (Edelstein et al., 2005).

Australian GPs implement opportunistic screening to identify individuals they (GPs) consider to be at HR. Although the Guidelines recommend the *AUSDRISK* be used to first identify HR prior to blood glucose testing, this is rarely done (Lee & Colagiuri, 2016) . Evidence for community screening is not strong and the consensus is that population screening is

expensive with low outcomes, and a belief that, where opportunistic screening is considered effective, that screening process should continue (Shaw 2017).

A more comprehensive assessment of each individual's pattern of dysfunction would be to implement a full fasting blood test, however it was considered unlikely to be cost-effective nor acceptable to individuals as a first step in a targeted screening process (Colagiuri, 2012, Lee et al., 2013, Lee et al., 2016). The most recent comment by Australian researchers was that T2DM screening was a balance between maximum identification of those individuals with undiagnosed T2DM or at HR, and the cost to achieve this. (Lee et al., 2018). Their research utilised data from the Australian Diabetes Obesity and Lifestyle Study (AusDiab) baseline and first follow-up study (AusDiab-2) as the basis for determining which of three screening scenarios was the most effective and cost effective for community diabetes screen and prevent T2DM. The recommended screening protocol for a local community-based diabetes prevention program was to combine an *AUSDRISK* assessment with a score ≥15 followed by blood glucose testing with either FPG or HbA1c. This combination was the most cost effective and the HbA1c test was the most convenient (and acceptable) test as it does not require a fasting blood sample, but it was acknowledged to be a less sensitive approach and may miss some individuals with T2DM/preDM. This recommended approach is essentially an opportunistic screening approach based within a community setting rather than a clinical setting.

2.11.11 Case-finding should be a continuous process, not just a "once and for all" project

The NHMRC Guidelines for the Case Detection and Diagnosis of Type 2 Diabetes recommend that opportunistic screening be undertaken every 3 years for those individuals whose last test showed them to be normoglycaemic. Individuals found to have elevated blood glucose levels/preDM should be re-tested annually and have lifestyle and or medication management implemented. However, as discussed previously in this chapter

there is no national system, recording of results or funding to ensure that this screening and case finding occurs on a regular basis.

Results in the Finnish Diabetes Prevention Study (Tuomilehto et al., 2001) and the US Diabetes Prevention Program (Edelstein et al., 2005) have shown that screening and early management/treatment during the asymptomatic stage improves the long-term outcome for those identified as having elevated blood glucose levels (Simmons et al., 2012). These intensive Diabetes Prevention Programs have shown a reduction for the risk of T2DM by 58.0% in adults with Abnormal Glucose metabolism (AGM) as shown by lifestyle changes and weight reduction, with/without medication. However there is still some ambivalence regarding the effectiveness of population-based T2DM screening in reducing mortality and morbidity (Waugh et al., 2013). There is general support for the cost-effectiveness of targeted screening to prevent/delaying the onset of T2DM. Australian research by Colagiuri provided evidence that although the cost to individuals and government, for the management of T2DM with/without complications was substantial, it could be significantly reduced by preventing initial development of T2DM and its complications (Colagiuri, 2012). For older individuals, this preventive approach has the potential for improving their quality of life.

2.12 Identification and case detection T2DM and preDM in Australia

There are no specific signs and symptoms to identify the ongoing and progressive nature of glycaemic dysfunction in the early stages of pre-DM/T2DM, thus individuals are not alerted to their increasing risk factor burden for developing pre-DM/T2D by experiencing early symptomatology (Waugh et al., 2013).

As stated earlier in this review, there are established Australian guidelines and procedures for identification and case detection of T2DM (Colagiuri et al., 2009a, Colagiuri et al., 2009b, Royal Australian College of General Practitioners and Diabetes Australia, 2016-18).

However, in practice, diabetes risk assessment has not been systematically implemented by GPs (Wong et al., 2011) with most GPs using a patient's clinic presentation (for a related or

unrelated condition) to opportunistically implement a biomedical assessment of a patient's glycaemic status (Shaw, 2017).

Prior to 2014, GPs would most likely advise a fasting blood sample to be tested for plasma glucose (FPG), cholesterol levels (LDL, HDL, triglycerides) with or without liver function tests for individuals presenting with obesity and hypertension.

In 2014, the Australian government introduced a specific Medicare payment code for one annual HbA1c test (Medicare item 66841) for individuals, not previously diagnosed as having T2DM, but assessed by their GP as being at HR for T2DM, or assessed as HR on completion of the *AUSDRISK*.

Other recommended strategies for the entry step in T2DM screening such as point-of-care testing with a non-fasting HbA1c test have been utilised in regional and remote Australian populations (Colagiuri, 2015, Degeling et al., 2012, Marley et al., 2015) and would warrant investigation to determine if this approach was/were more effective, efficient and acceptable to the older age cohort (Thompson et al., 2016), for identifying those with pre-DM/T2DM.

2.12.1 Opportunistic screening

A recent commentary by Shaw (Shaw, 2017) stated there was little evidence of benefit related to a population screening program for T2DM. This was due to the effectiveness of high levels of opportunistic screening in the general population where the outcome of the initial opportunistic screening procedure was followed by regular follow-up assessments. However, without systematic follow-up screening, the individual opportunistic approach for identifying those adults with or at high risk of T2DM does not identify an ongoing pattern of potentially increasing hyperglycaemia, nor does it establish a consistent system for regular testing and recording results for incident T2DM/preDM.

In the Australian primary health system, patients are not registered with a particular GP or group general practice. Although patients are encouraged to attend one GP/GP practice to

maintain consistency with healthcare, there is no regulation to do so and for a variety of reasons, patients (with or without their medical records) move between GP providers. The National Diabetes Services Scheme (NDSS) database (Australian Government Department of Health, 2016) maintains records (with annual updating) of those individuals newly diagnosed with diabetes (if registered on the NDSS by their GP), and total annual numbers of those with diabetes (all types) by gender and age-range, but does not include those with non-diabetic hyperglycaemia – Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance and elevated HbA1c (higher than normal but not reaching the T2DM diagnostic point).

The NDSS database is accurate for people with type 1 diabetes as they access the NDSS for insulin supplies and services. However, there is less accuracy for T2DM particularly those not requiring insulin supplies and services, as recording is not mandatory. A recent survey by the non-government organisation *Diabetes Tasmania* reports that 48% of GPs in Tasmania did not complete NDSS registration for their patients with diabetes (2017 personal communication).

In comparison, healthcare services in the UK, US and European countries have established primary healthcare systems in their public health (UK, many European countries) or private health (as is the case with the Private Health Insurance companies in the US). These primary healthcare systems utilise patient and GP identifiers; patients are allocated/attached to particular primary health practices, and the frequency and results of medical tests are recorded as part of quality assurance. At a national level for each country/province, primary healthcare results are recorded and utilised for policy decisions and changes in direction to address documented health needs as evidenced by the development and subsequent review of the NHS Health Check program (Martin et al., 2018, Robson et al., 2016).

2.13 T2DM screening initiatives within time-limited type 2 diabetes prevention programs in Australia

In many Australian states (NSW, Vic, QLD, WA) but not Tasmania, the *AUSDRISK* is used to identify HR individuals to participate in time-limited initiatives and programs for T2DM prevention (Dunbar, 2017, Johnson et al., 2015, Malo et al., 2015, Vita et al., 2016). These programs mainly address the modifiable lifestyle risk factors for T2DM – overweight/obesity; insufficient physical activity; increased sedentary behaviour; and poor/over nutrition (Colagiuri et al., 2009c, Dunstan et al., 2004, Halter et al., 2014, Kalyani et al., 2013). Community pharmacies in Australia have also conducted T2DM screening initiatives using *AUSDRISK* to identify those at HR and advise them to attend their GP for a biomedical assessment. Eligible participants were adults without diabetes, 18–74 years (Kilkenny et al., 2014, Krass et al., 2017, Krass et al., 2007). Similarly, the NGO *Diabetes Australia* and its state-based organisations provide access via their websites to the *AUSDRISK* for individual self-assessment of T2DM risk but there is no component to check HR individual follow-up, to attend a GP for biomedical assessment.

There appears to be an ambivalent attitude in Australia to screening for earlier detection of chronic conditions. With limited financial support or no additional support for additional work required for screening, some governments and health management systems have difficulties justifying long term benefit against significant short-term cost for additional screening and consider that funding is better utilised for management of those with diagnosed T2DM (Shaw, 2017).

2.14 International type 2 diabetes screening programs

Review of the literature on screening for T2DM internationally shows that there is still not consensus that population screening for T2DM, even within a specified age range, is effective and efficient, as the expense and coordination is out of the reach of many Governments/countries (Shaw, 2017, Simmons et al., 2017, Simmons et al., 2012).

Most developed countries conduct 2–3 step T2DM screening procedures, by first implementing an initial risk assessment tool /test to identify those individuals at HR, prior to implementing a biomedical assessment. Many countries have developed their own Diabetes Risk Assessment tool based on findings from their own population prevalence studies (Aujla et al., 2013).

International T2DM screening/identification/prevention programs are most frequently targeted to individuals in the 45–60 years age group with some increasing the upper age level to 75 years ((Bergmann et al., 2007, Escobar et al., 2015, Hauner et al., 2008, Martin et al., 2011, Rathmann et al., 2005, Rey et al., 2012, Van Den Donk et al., 2011) for individuals exhibiting known risk factors for T2DM – overweight/obesity; family history; hypertension and abnormal lipid levels. New Zealand has diabetes and prediabetes screening as part of cardiovascular risk assessment which begins prior to 45 years in high risk groups (e.g. Maori, Pacific, obese) and extends beyond 60 years. See - https://www.health.govt.nz/publication/cardiovascular-disease-riskassessment-

and-management-primary-care. Some studies have used Risk Assessment Tools, with varying success and others have used direct implementation of blood testing.

2.14.1 Real world national screening programs

In the UK the *NHS Health Check* (Robson et al., 2016) is a national preventive program to reduce cardiovascular morbidity in individuals aged 40–74 years. It has been conducted from selected medical practices and pharmacies since 2009. Although experiencing initial difficulties in establishment, it has shown year-on-year improvement. A systematic review by Harte E et al 2017, found that the reasons for not attending included lack of awareness or knowledge, misunderstanding the purpose of the *NHS Health Check*, aversion to preventive medicine, time constraints, difficulties with access to general practices, and doubts regarding pharmacies as appropriate settings. The findings particularly highlighted the need for improved communication and publicity around the purpose of the *NHS Health Check*

programme and the personal health benefits of risk factor detection. The *NHS Health Check* is now a well-established system with results showing the effectiveness of combined screening of cardiovascular and T2DM (introduced in 2016). Among the attendees, new cases of hypertension (38/1000 checks); new cases T2DM (9/1000 checks); chronic kidney disease (4/1000) were found. Of those found to be at high CVD risk 19.3% were newly prescribed with statins and 8.8% newly prescribed with antihypertensive therapy. Those identified with T2DM were referred for medication and/or lifestyle management. However, a recent retrospective evaluation of the performance of the NHS Health Check program was critical of its ability to identify people at high risk of developing T2DM with results showing a failure to identify a third of people at HR of having or developing T2DM (Martin et al., 2018). In the US, T2DM screening-to-treat programs are well-established for those individuals with health insurance whereas those without health insurance are not well covered (Diabetes Prevention Program Research Group 2019). Community based and faith-based programs have been implemented in Europe and UK for under-privileged and non-insured individuals and families (Wareham et al., 2011) (Chang et al., 2016, Robson et al., 2016) (Aujla et al., 2013, Groenenberg et al., 2015, Van Den Donk et al., 2011).

Apart from formal screening-to-treat programs (Aujla et al., 2013), opportunistic screening is utilised in primary health care and acute care – medical GP practices, blood banks, and allied health – optometry, pharmacy, dental clinics (Anghebem-Oliveira et al., 2017, Charfen et al., 2009, Cogneau et al., 2006, Holm et al., 2016, Howse et al., 2011, Klein Woolthuis et al., 2009, Krass et al., 2007). Opportunistic screening utilises a 2–3 step approach by using risk factor assessment questionnaires as the first step. Although many countries/populations have their own risk factor questionnaire, the use of *FINDRISC* (Finnish Diabetes Risk Assessment tool) or the simplified *FINDRISC* has been found to be the “most generic” of the European T2D risk assessment tools (Tuomilehto et al., 2001). However, this approach has not been universally successful (Bergmann et al., 2007). The *FINDRISC,* developed in 2003, was the first non-invasive Risk Assessment tool for identifying individuals with or at HR for T2DM and has been the “proforma” for all subsequent T2DM risk assessment tools. In 2012,

Hellgren et al (Hellgren et al., 2012) evaluated the performance of the *FINDRISC* questionnaire to identify individuals with IGT in Swedish primary care. Results showed that the *FINDRISC* questionnaire was a useful instrument for identification of individuals with impaired glucose metabolism (HR) but seemed less effective for detection of individuals with impaired glucose tolerance (very high risk/prediabetes). The researchers (Hellgren et al) concluded that methods other than *FINDRISC* were needed to identify IGT patients for implementation of lifestyle changes.

A systematic review conducted in the UK by Khunti et al (Khunti et al., 2015) found that using 3–4 steps in the process to increase the participation rate and confirm high risk, prior to implementing an OGTT, was the most effective and cost-effective procedure for identifying individuals with different levels of glycaemic dysfunction (Khunti et al., 2015). There are a smaller number of studies for screening for T2DM in adults older than 60 years. Studies by Dankner et al (Dankner et al., 2009, Dankner et al., 2015) have recommended a "personalised approach" for detecting preDM and T2DM with direct biomedical assessment rather than implementing a preceding risk assessment test. Similarly Escobar et al (Escobar et al., 2015), found that conducting a direct biomedical assessment study (without an initial risk assessment procedure) was effective in identifying the prevalence of unknown impaired glucose metabolism (prediabetes) and unknown (undiagnosed) T2DM in apparently healthy Swiss senior citizens.

International studies have found that the major facilitating components to achieve effective screening procedures are well-established health systems and e-records – in GP practices, in UK; Europe (Klein Woolthuis et al., 2007, Schwarz et al., 2008); and in the US for those with private health insurance (Diabetes Prevention Program Research Group 2019). Participation in screening for T2DM is also facilitated by first raising health awareness in the whole population, for example in the US Diabetes Prevention Programs and the Finnish screening and prevention programs, prior to implementing a screening program (Guess et al., 2015, Schwarz et al., 2008).

Additionally, raising awareness of T2DM and preDM in specific high-risk cohorts, such as the older age cohort, has been found to be effective in promoting participation in ongoing screening. This was shown in the Swedish screening program for identifying abnormal glucose levels in healthy older adults (Escobar et al., 2015).

Generally, the initial use of Risk Assessment tools to identify those at HR prior to blood glucose assessment is promoted as being cost effective (Colagiuri, 2012, Lee et al., 2013) However, studies and systematic reviews by Noble and others (Abbasi et al., 2012, Noble et al., 2011), found that most basic T2DM risk factor screening questionnaires could identify people at HR for developing T2DM in a 5-10 year time frame. But at the time of implementation, most screening questionnaires over-estimated the actual risk of T2DM and did not clearly indicate the HR participants' glycaemic status, nor whether there was a requirement, or not, for blood glucose assessment. Risk Assessment Tools (RATs) have been developed using findings from prevalence studies of T2DM in a particular population and therefore are not as applicable when being used as a contemporaneous screening tool. Nevertheless the NHMRC Guidelines for Case Detection and Diagnosis of Type 2 Diabetes and Primary Prevention of Type 2 Diabetes (Colagiuri et al., 2009a, Colagiuri et al., 2009b, Royal Australian College of General Practitioners and Diabetes Australia, 2016-18) recommend use of the *AUSDRISK* as the first step in a T2DM screening process to first identify individuals at HR. Results from Dunbar et al. and Malo et al. (Dunbar et al., 2015) (Malo et al., 2015) in a middle-aged cohort are suggestive that *AUSDRISK* may also overestimate actual risk. However, it may not be an inaccuracy in screening results, but rather that a risk assessment tool, designed to estimate future risk, is not very accurate when used as a contemporaneous screening tool.

2.15 Barriers to T2DM screening – national and international

Patient acceptability is critical to the effectiveness of a screening program. Patient acceptability was investigated as part of the MY-WAIST STUDY for T2DM screening (Aujla et al., 2013) conducted in UK Primary Health care (GP Practices). Low recruitment (8.6%)

was influenced by participants' beliefs regarding likelihood of developing T2DM with those attending showing greater perceived susceptibility, whereas lack of perceived severity of T2DM was more common in those who did not attend. Many participants indicated their belief that early identification of T2DM was considered to be less necessary than for conditions involving cancer.

Practical aspects about this screening strategy such as having to complete an OGTT – lengthy appointment; 2-hour wait; having to undergo overnight fast; dislike of a highly sweetened drink were barriers to those who did not attend. Other findings were that older people and those with a family history were more likely to attend, as were the "worried well", but those who did not attend the GP practice on a regular basis were less likely to attend. There were procedural difficulties in that clinicians did not respond uniformly according to Guidelines, with regard to the blood test ordered and presentation of a screening assessment result. In addition, many practice staff considered implementing this study made additional work or disruption to the usual work routine and imposed additional stressors (Mainous 3rd et al., 2016b). Screening studies conducted subsequent to the MY-WAIST study (Aujla et al 2013) have found similar logistical barriers mainly due to the lack of familiarity with the process or lack of a regular well established and funded system.

In a systematic review Dhippayon et al (Dhippayon et al., 2014) reviewed 24 studies which had implemented Risk Assessment Tools, and noted barriers reported by health care professionals and participants in completing the Risk Assessment Tools. Health care professionals were concerned with the increased time and lack of remuneration whereas individuals expressed a range of attitudes, from concern about the severity of T2DM to considering it not as severe as other chronic conditions. Only five of the 24 studies included a follow-up blood glucose test component, which participants could either complete or not. In this systematic review (Dhippayon et al., 2014), the only Australian study included had been conducted by Wong et al (Wong et al., 2011). This study comprised a survey of 78 GPs to

determine their knowledge and use of *AUSDRISK.* The findings revealed that the knowledge and application of *AUSDRISK* to be low.

In a series of studies Godino et al (Godino et al., 2014a), reported that GPs offered only limited reinforcement of the importance and benefit of lifestyle changes and 1-3-year re-test of blood glucose as part of a T2DM screening initiative. This lack of emphasis appeared to inadvertently reduce the HR individuals' perception of their T2DM risk (Godino et al., 2012, Godino et al., 2016).

GPs appeared to be responding to a current normoglycaemic status of the older individual rather than their ongoing HR status – a missed opportunity to explain the complexity of interpreting and communicating HR status to patients and further reinforcing effective behaviour change to decrease/stabilise their risk for preDM/T2DM (Mainous 3rd et al., 2016a).

2.16 Health literacy/knowledge of type 2 diabetes

The general public's knowledge of T2DM appears to be that lifestyle factors alone increase or decrease the risk of T2DM whereas the research findings emphasise the complexity of the interactions between modifiable and unmodifiable risk factors for T2DM. Information available on Australian Government and non-government health websites such as the Diabetes Australia Fact Sheets (Diabetes Australia, 2017a, Diabetes Australia, 2017b) provide general information in relation to types of diabetes, risk factors and complications:

> *"It is a progressive condition in which the body becomes resistant to the normal effects of insulin and/or gradually loses the capacity to produce enough insulin in the pancreas. We do not know what causes type 2 diabetes. Type 2 diabetes is associated with modifiable lifestyle risk factors. Type 2 diabetes also has a strong genetic and family-related risk factors"(Diabetes Australia, 2017b).*

Although this information may hint at the complexity of the condition, the fact that *"initially it can often be managed with healthy eating and regular physical activity and losing weight"* tends to simplify the message and push the responsibility for success or failure solely on the individual.

Reviewing the research literature provides a picture of a very complex disease with many factors and interactions yet to be identified and accurately documented. In 2017, researchers Skyler et al (Skyler et al., 2017) reported on the outcomes of a research symposium conducted in October 2015 by the American Diabetes Association (ADA), the Juvenile Diabetes research Foundation (JDRF), the European Association for the Study of Diabetes (EASD), and the American Association of Clinical Endocrinologists (AACE) to address the genetic and environmental determinants of type 1 and type 2 diabetes risk and progression, as well as complications. The purpose was to acknowledge the heterogeneity and complexity of diabetes and to determine appropriate therapeutic approaches based on disease pathophysiology and stage. The outcome was that personalised medicine was still very much a "work-in-progress" with the future direction being to address the gaps in knowledge on the phenotypes and genotypes of the subtypes of diabetes. This essential research needed to be integrated with other research promoting early identification of T2DM risk, and regular T2DM screening to avert or reduce the impact of this complex condition.

A series of studies published in Germany by Genz et al in 2010–2014 (Genz et al., 2010, Genz et al., 2012, Genz et al., 2014) found that providing information about T2DM and preDM improved recipients knowledge, but had little impact in T2DM screening participation. In the Netherlands, Groenenberg et al (2015) found that there was little difference in the method of approach for screening (face-to-face or mailout) but the greatest improvement in screening attendance was follow-up contact by mail or telephone to remind individuals to attend. Finally, those who had not responded were contacted directly by their GP. Using this approach achieved a 70 per cent participation rate in completion of a risk assessment test, but in this study, there was no follow-up biomedical assessment.

2.17 Health risk and perceived health risk and readiness to change

People with undiagnosed T2DM or preDM considerably underestimate their probability of having or developing diabetes. Contrary to associations with actual diabetes risk, perceived diabetes risk was lower in men (Davey et al., 2015), in lower educated and in older persons. In a study conducted in the Netherlands by Adriaanse et al (Adriaanse et al., 2008), both low risk and high risk profile subjects perceived diabetes as a serious disease. Perceived risk of having diabetes was slightly lower for the low risk compared with the high-risk profile subjects. However, even among those with a high-risk profile for T2DM, almost half appeared not to know their risk. In addition, this study found that perceived risk decreased with increasing age, whereas actual risk increases with increasing age.

Anderson-Lister and Treharne (Anderson-Lister et al., 2014) identified four themes that influenced an individual's participation in screening for T2DM: knowledge of diabetes, power to influence diabetes, limitations of responsibility or blame for diabetes and feelings about individuals with diabetes. Studies by Grzywacz et al (Grzywacz et al., 2011, Grzywacz et al., 2014) found that beliefs about diabetes could be organised into a discrete number of belief domains, such as "causes" and "consequences". Across individuals there is heterogeneity in the beliefs about cause and consequence, however at an individual level, there is remarkable consistency in beliefs about diabetes, both in content and over time. Personal experiences are a strong force in creating and maintaining beliefs about disease – with reference to causes and management. These responses towards diabetes management are likely to be shown in screening and the decision whether to participate in screening. Furthermore patterns and stability of beliefs are more stable in older adults and less likely to change (Bouchard et al., 2012).

The impact of poor or limited health literacy in Australia is well documented by the National Statement on Health Literacy – Time to Take Action (Australian Commission on Safety and Quality in Health Care, 2014) and research by Jayasinghe (Jayasinghe et al., 2016) on the impact of health literacy and life style risk factors on health-related quality of life of Australian

patients. In addition, stigma towards those with diagnosed T2DM as having been responsible for the condition, by poor health behaviour, has been reported in the recent MILES-2 study in Australia (Ventura Ad et al., 2016). This attitude along with poor health literacy has been noted in studies internationally (Hivert et al., 2009, Vassy, 2013).

Behavioural responses to actual risk, both positive and negative, impact on participation in screening initiatives. Experience of risk as “measured vulnerability” is well-known in the disinclination of HR male participants with an increased perceived health threat leading to decreased attendance to follow through to diagnosis (Ajzen, 1991, Davey et al., 2015, Godino et al., 2014a), and would be an issue to be addressed with males being at greater risk for T2DM than females (Australian Bureau of Statistics, 2011-12, Dunstan et al., 2002b). The ADDITION-Cambridge study (Echouffo-Tcheugui et al., 2015, Paddison et al., 2009) reported that negative screening results did not lead to positive or negative lifestyle modification over a 7-year follow-up. Overall, this lack of behavioural change would suggest that in order for T2DM prevention, screening and management to be effective, it would need to be embedded in strong systems methodology, as recently recommended in the evaluation of the *National Health Service Health Check on Cardiovascular Disease Risk* (Chang et al., 2016). This would be of specific importance for those groups known to be at HR for T2DM such as older age individuals, many of whom have mainly non-modifiable risk factors specific to their age.

2.18 Issues for T2DM screening in Australia

Effectiveness of screening strategies need to be determined by a balance between sensitivity and specificity of the population requiring further testing; the convenience and acceptability of screening by the participants, and the cost of screening. Cost is of particular concern to health providers as the cost of delivering health care continues to escalate (Colagiuri, 2012).

In Australia opportunistic screening via general practice is not supported by strong systems for recording and reviewing patient outcomes. Continuing this practice as the main strategy

for identifying individuals with or at high risk for T2DM, without it being embedded in strong systems methodology, needs careful review. GPs appear to respond to the current health status of older individuals rather than their potential HR status due to increasing age. This appears to be a missed opportunity by GPs to educate older patients to the benefits of effective lifestyle approaches for a wide range of conditions and the importance of annual or bi-annual screening for T2DM. Unfortunately, it is likely that the time limits under which GPs work in Australia are restricting the possibility for implementing a consultative approach to chronic disease prevention and self-management. The length of time for a standard GP appointment is 10-15 minutes (www.betterhealth.vic.gov.au).

Although the *AUSDRISK* risk assessment tool has been available since 2008, it has rarely been utilised by GPs and other healthcare practitioners as part of an opportunistic screening process for identifying those individuals with or at high risk for T2DM. The *AUSDRISK* highlights the range of factors that influence risk for T2DM. The lack of *AUSDRISK* use is a further missed opportunity to educate individuals on the wide range of risks for developing T2DM and they remain generally unaware of the impact of older age on the risk for T2DM (Johnson et al., 2015, Laws et al., 2012, Vita et al., 2016).

With regard to the estimated 5–10-year latent period in the development of T2DM from preDM, consideration of preDM/T2DM screening on a routine basis for older age adults from age 60 years onward would be warranted. This timeframe for T2DM screening could be similar to the 5-yearly Australian bowel cancer screening (55–70 years) and bi-annual breast cancer screening (50–74 years) (Australian Government).

2.19 Conclusion

To my knowledge, the *AUSDRISK* has not been used in Australia in a systematic manner as the first step in a targeted community-based screening procedure in a cohort of older individuals, and to follow them through to biomedical assessment. The aim of this study is to determine the feasibility (distribution), acceptability (uptake) and effectiveness (finding HR

and T2DM) of implementing the *AUSDRISK* specifically to this high risk group of community-living adults aged 60 years and older, with follow-up biomedical assessment if recommended, in a real world T2DM screening scenario (Wareham et al., 2011) for older age individuals in Tasmania.

2.20 Implementation project

- The *AUSDRISK* was implemented as recommended by *NHMRC National Evidence based Guideline for Case Detection and Diagnosis of Type 2 Diabetes* for T2DM screening in the *young-old* adult cohort (60 years and older) in Tasmania, Australia
- Determined the feasibility and acceptability (distribution and uptake) of implementing the *AUSDRISK* in a real world setting of older adults
- Determined the effectiveness of the *AUSDRISK* for identifying older adults with or at HR for developing T2DM
- Documented the follow-up the actions of those assessed as HR and the actions of their GPs in implementing a biomedical assessment of those older individual assessed as High Risk on the *AUSDRISK*
- Documented the facilitators and barriers to community-based screening of older adults by following the *National Evidence based Guideline for Case Detection and Diagnosis of Type 2 Diabetes* for older adults with or at High risk for type 2 diabetes

2.20.1 Project methodology

This study had two main phases. Phase 1 comprised the recruitment and completion of *AUSDRISK* by older individuals via either a Direct approach (health services) or an Indirect (mail-out) approach, with an invitation for participants to voluntarily self-assess their risk for T2DM by completing the *AUSDRISK* and to follow the *AUSDRISK* recommendations for their assessed level of T2DM risk. Phase 2 comprised documentation via a survey and recording

via semi structured interviews, focusing on the follow-up actions of the participants assessed as HR; their GP actions; and the HR participants' biomedical assessment results (Diagnostic category only: Normal; EBG;T2DM).

2.20.2 Eligibility

The primary eligibility requirement for participants recruited for this study was to be aged 60 years or over. Exclusion criteria for Direct recruitment of individuals via the health service settings included previous diagnosis of diabetes, cardiovascular diseases or neurologic diseases that could compromise an individual's ability to participate in the study; any admissions for community palliative care treatment at home; or an inability to reliably understand the English language, even with assistance. The only exclusion criteria for those recruited via SC mailout was a diagnosis with any form of diabetes.

2.20.3 Recruitment

This *AUSDRISK* screening study was conducted over a 6-month period. It utilised a cross sectional survey of older general community members using the *AUSDRISK* questionnaire with a follow-up survey of those assessed as HR to document their actions (re biomedical assessment) on being advised of their HR status. There were two methods of recruitment. Direct recruitment (face-to-face) with screening being conducted in two health care settings in Southern Tasmania over a 6 week period (within the 6-month period): a community health centre (public health) servicing a low socio-economic status (SES) outer metropolitan community and two metropolitan optometry practices (private health). Indirect recruitment (mail out) and screening utilised three State Government statewide *Seniors Card* (SC) mail-outs to access older individuals aged 60 years and over. At the time the project was conducted (2014–15) there were over 96,000 older Tasmanians recorded on the SC database with 450–500 new/renewed cards mailed out every 4-6 weeks.

2.20.4 Direct recruitment

Direct recruitment was achieved via, health professionals or clinical admission staff inviting individual adult outpatients to complete an *AUSDRISK* as an assessment of their risk for T2DM not a diagnosis of T2DM (diagnosis only via blood test ordered by a GP. Participation was voluntary. Informed consent was obtained. The process for completing the *AUSDRISK* was explained and assistance offered for waist measurement. Those who scored HR (12 points or more) were invited to complete a follow-up survey (by phone or email) in 5-6 weeks to advise what measures they had taken towards having a biomedical assessment of their blood glucose level. Completing a follow-up survey was voluntary. If agreeing, participants provided their preferred contact details.

2.20.5 Indirect recruitment

Indirect recruitment was achieved via three *Seniors Card* mail-outs over a 6-month period. Permission was granted to utilise only three mail-outs. With each mail out, in addition to the SC, the recipients received an *AUSDRISK*, an information/instruction/consent form, an invitation to self-assess their diabetes risk status and a reply-paid envelope to return documents. The documentation also included an invitation specifically for those who self-scored HR on the *AUSDRISK* to participate in a short follow-up survey and, if agreeing, to provide additional written consent, contact details and a request to return all documentation in the reply-paid envelope.

2.20.6 HR follow-up survey

A short follow-up survey offered to those who scored HR was conducted 5-6 weeks after completion of the *AUSDRISK,* by phone or email. The survey comprised 8 questions relating to the HR participants' follow-up actions after completion of the *AUSDRISK* including their attendance/non-attendance at a GP practice for biomedical assessment and if attending, their GP's actions and recommendations and blood test results indicating their current glycaemic status. As part of the follow-up survey, HR participants were invited to comment

on their prior awareness of *AUSDRISK* and on the questions contained in the *AUSDRISK* risk assessment questionnaire.

2.20.7 Data recording

De-identified quantitative data was recorded on Excel spreadsheets from the information/consent forms and online survey forms. De-identified qualitative data was compiled from paper-based standardised records of the interview for the follow-up survey and from paper-based records of the participating health professional and administrative staff and recorded on Excel spreadsheets. All data was kept securely as per requirements in the *Tasmanian Health and Medical Human Research Ethics Committee* documentation for data storage. The data was kept in locked cupboards/filing cabinets with access only via a key held by one designated person at each site and by researcher, Elizabeth Bingham.

Full details of Methodology are covered in Chapter 3.

Chapter 3. Methodology

3.1 Introduction

In this chapter, the philosophical viewpoint, theoretical underpinning, ethical considerations and the rationale for the methods utilised in this research will be addressed. In addition, the methods utilised in developing the Literature Review and the *AUSDRISK* research project will be discussed.

The *AUSDRISK* Assessment Tool has been available since 2010, and is recommended by Australian Medical Guidelines to be used as the first step to identify those at HR when screening for T2DM. The *AUSDRISK* has had limited use by GPs (Wong et al., 2011) or in health promotion (Diabetes Australia, 2017a). This study aimed to take a pragmatic real-world approach (Glasgow et al., 2013) to disseminating the *AUSDRISK* within the older age cohort in Tasmania, Australia. In addition, the study was designed to identify any stakeholder issues that may be negatively impacting on the use of *AUSDRISK* as the first step in T2DM screening as recommended by the NHMRC Guidelines for the Case Detection and Identification of Type 2 Diabetes (Colagiuri et al., 2009c). By taking a comprehensive approach, information may become available to drive quality improvement (Glasgow et al., 2013) in screening for T2DM, particularly in the older age group.

3.1.1 Epistemology

In scientific research there are two major paradigms used to determine what is knowledge and how it may be established, investigated, ratified and viewed. The two paradigms – empiricism and constructionism are different in perspective.

From the perspective of empiricism, which is the foundation of positivism – reality/knowledge is viewed as universal, objective, quantifiable and replicable. Therefore, from this standpoint it is argued that reality is the same for everyone and via the application of science, that shared reality can be identified. Research based on a positivism paradigm may utilise a quantitative approach.

As opposed to positivism, the basic premise of the constructionist approach is that reality is socially constructed by and between the persons who experience it (Gergen, 2015).

The constructionist view is that reality is a consequence of the context in which the action occurs and is shaped by the cultural, historical, political and social norms that operate within that context and time. As such, reality can be experienced quite differently for each individual.

The constructionist approach views the individual as a “sense maker”, in that each individual seeks to understand or make sense of the world from their own experience. Social constructionism (Gergen, 2015) provides a different perspective from which to view the world that allows for the unique differences of individuals to influence their perception of reality, whilst at the same time, permitting the essential “sameness” that unites human beings to be identified (Andrews, 2012). Research based on a constructionist paradigm may utilise a qualitative approach.

A methodological movement – Pragmatism – which addresses elements of both the positivism and constructionism approaches has emerged to overcome the quantitative-qualitative dichotomy and reduce the tensions between these different paradigms (Glasgow et al., 2013 , Teddlie et al., 2010). Multimethod research is a pragmatic comprehensive approach which is utilised frequently in health science research to gain a greater understanding of the complexities within health science and address questions that may have not been fully answered by either quantitative or qualitative approaches implemented alone. A multimethod research design may be quantitatively or qualitatively driven with the alternate approach providing the supplementary material.

3.1.2 Multimethod research

The multimethod research used in this study was a quantitatively-driven approach/design with qualitative data added to supplement and improve comprehension of the quantitative results. A key characteristic of the multimethod approach is the capacity for integration at all

levels of the research study from design level through to the methods level and finally integrating interpretation and reporting of results.

In 2010, Tashakkori & Teddlie (Teddlie et al., 2010) identified seven reasons often given for using a multimethodology approach.

1. Complementarity – to integrate two different but connected answers to a research question: one reached via a quantitative approach and the other by means of a qualitative one.

2. Completeness – to gain a greater understanding of the phenomenon under investigation by merging qualitative and quantitative findings.

3. Development – to use the first phase of the study to obtain research questions, data sources or sampling frameworks for the second phase of the study.

4. Expansion – as in “development” but with the aim of elaborating on the information obtained in the first phase of the study.

5. Confirmation – to determine the integrity of the inferences attained from the study by means of integrated methods.

6. Compensation – to compensate for the weaknesses of one method via the strengths of the other.

7. Diversity – to compare and contrast divergent representations of the same phenomenon.

The choice of the multimethod approach in this research was triggered by aiming to achieve complementarity, completeness, development, expansion and confirmation in relation to implementing the Type 2 Diabetes Risk Assessment Tool (*AUSDRISK)* (Chen et al., 2010) for community-based screening to identify older age individuals with undiagnosed T2DM or being at High Risk of T2DM. The multi-method approach as described by Fetters et al., (2013).

The multimethodology structure for this study was *explanatory sequential* at the design level, then via *multi-stage* inputs from each of the recruitment settings. Quantitative analysis of the first stage (Phase 1) will allow for identification of the number of older individuals who scored High Risk (HR cohort) on the *AUSDRISK*. In the second stage (Phase 2), this HR cohort will then *form/build* the next database to complete a follow-up survey which will expand the quantitative data collected in Phase 1, and document additional qualitative data on beliefs and attitudes towards screening for T2DM risk. The quantitative data and qualitative data will be integrated at the interpretation and reporting levels. A narrative approach will be used at the final stage of the interpretation and reporting level (Fetters et al., 2013)..

3.1.2 Cross-sectional survey.

A cross-sectional study design Busk (Busk, 2014) was chosen for a number of reasons. This research study was a population-based survey to gain a snapshot of a range of older persons aged 60 years and over (excluding those with diagnosed diabetes) with respect to their risk for T2DM as assessed by their results on the *AUSDRISK*. The survey was a community-based one-off presentation/exposure of *AUSDRISK*. Further implementation of *AUSDRISK* in this cohort was dependent on the success of finding those with or at HR for T2DM (outcome). As such it was a pilot study by solely using an older-age cohort, the two methods of distribution, and the resultant uptake and completion of the *AUSDRISK*. The findings of which could be used in future public health screening for T2DM in older age individuals and developing T2DM prevention activities relevant to the older-age group. Following the distribution of *AUSDRISK*, the actions of those older individuals at HR towards determining their current glycaemic status were recorded via the follow-up survey questions (on line or via phone).

3.1.3 Quantitative and qualitative components of the multimethod design

The quantitative component of the multimethod design included: the initial participation rate of older individuals invited to assess their risk for T2DM by completing the *AUSDRISK*; the number who scored HR, and the number at HR who completed the full screening process to

biomedical assessment. In order to sample a wide range of community-dwelling older adults, three different settings were utilised to access and recruit older-age individuals. Due to Ethics commitments the study was required to additionally offer completion of the AUSDRISK to adults aged 50 years and above in the health service settings. The first setting was a public health integrated community health centre providing individual or multiple allied health services for community members of all ages for a short period to improve their functionality. The second setting comprised two private optometry practices used by the older community for maintenance of health and well-being (e.g. review of eye health status and prescription of lens to improve visual acuity). The third setting was an age-related statewide mail-out service for the Seniors Card (Australian Government, 2019b) available to all individuals 60 years and over who are not employed for more than 20 hours per week. This mailout service was chosen to achieve statewide distribution of the *AUSDRISK* which had the potential to reach those individuals who were not regularly accessing medical/health services.

The qualitative component of the multimethod research design complemented the quantitative component, by utilizing multiple choice sections in the survey, and a semi structured interview utilizing the survey questions, via phone. These methods, and particularly the latter, elucidated the HR individuals' experience in participation (voluntary) in a community-based T2DM screening initiative; their knowledge of T2DM and its risk factors; their knowledge of the *AUSDRISK* as a risk assessment tool for predicting T2DM risk, and their knowledge of the subsequent steps, that must be completed for those identified at HR to have their glycaemic status biomedically assessed by a general practitioner (GP).

3.1.4 AUSDRISK assessment tool

The Australian Type 2 Diabetes Risk Assessment Tool (*AUSDRISK*) was developed in 2008 by the Baker IDI Heart and Diabetes Institute on behalf of the Australian, state and territory governments, as a screening tool to identify those at high risk of developing T2DM (Chen et al., 2010). It was based on the findings nationally from approximately 6,000 adults who had participated in both the original Australian Diabetes Obesity and Lifestyle study in 1999-2000

– *AUSDIAB* (2000) (Dunstan et al., 2002a) and the 5-year follow-up AUSDIAB-2 (2005) (Chen et al., 2011) study. In development of the *AUSDRISK*, a range of factors was considered for inclusion, including alcohol, smoking and obesity, but only the risk factors that were the best predictors of the development of T2DM were included in the score. The risk factors are age, gender (male), nationality (where born); family history of diabetes; being diagnosed with high blood glucose (including gestational diabetes mellitus); taking medication for high blood pressure; smoking; not eating vegetables or fruit daily; less than 2.5 hours of physical activity per week; waist measurement (cm) (score adjusted for gender and height). Each factor is allocated a score (depending on its impact on risk for T2DM) and the Total Score is the sum of the scores of the individual risk factors. The *AUSDRISK* has been validated in three other Australian studies ((Dunbar et al., 2015, Dunbar et al., 2014, Malo et al., 2015) as a predictor of diabetes risk at 5-year follow-up and has been acknowledged internationally as a valid and reliable pre-screening test to identify people at HR for developing T2DM within a 5-year period (Kegne et al., 2014, Noble et al., 2011).

3.2 Methods

3.2.1 Literature search

In consultation with a University of Tasmania (UTAS) research librarian, a series of literature searches were conducted using a systematic and comprehensive search strategy. These were completed and then updated first in 2017 and again in 2019.

With the epistemological foundation of the research design in mind a detailed literature search covering both quantitative and qualitative elements in relation to T2DM screening processes, nationally and internationally, was undertaken to review the rationale, risk assessment procedures, the facilitators, and barriers to the uptake of health screening for older adults, with emphasis on type 2 diabetes and its precursors prediabetes/ non-diabetic hyperglycaemia.

3.2.2 MeSH search terms

Table 3.1 MeSH search terms

MEDLINE	CINAHL	SCOPUS
MeSH TERMS. Diabetes Mellitus, type 2 OR. Prediabetic state OR. Hyperglycaemia OR. Title/Abstract: Pre-diabetes OR type 2 diabetes OR prediabetic OR prediabetes OR hyperglycaemia OR hyperglycaemia OR impaired glucose metabolism. AND. MeSH Terms: Risk factors OR. Precipitating factors OR. Title/Abstract: Risk factors OR risk. AND. MeSH terms: asymptomatic disease OR. Title/Abstract: undiagnosed. AND. MeSH: no exp. Surveys and questionnaires OR. health status indicators OR. MeSH Terms: risk assessment OR. Title/Abstract: Screening OR. Risk Assessment Tool OR. Assessment Tool. AND. MeSH: no export. Aged OR. Title/Abstract: Older adults OR. Older age OR. Older individuals OR. People over 60 years OR. Young-old OR. Seniors OR. Elderly	MH Exact Subject Heading. Concept 1: • Diabetes Mellitus, Type 2. • Prediabetic State. • Hyperglycaemia (explode): (MH “Hyperglycemia+”) –. • Concept 2: • Structured Questionnaires. • Questionnaires. • Health Screening. • Risk Assessment. • Concept 3: • Aged. • Concept 4: • No CINAHL Headings. • Concept 5: • Risk Factors (explode): (MH “Risk factors+”).	MH Exact Subject Heading. Concept 1: • Diabetes Mellitus, Type 2. • Prediabetic State. • Hyperglycaemia (explode): (MH “Hyperglycemia+”) –. • Concept 2: • Structured Questionnaires. • Questionnaires. • Health Screening. • Risk Assessment. • Concept 3: • Aged. • Concept 4: • No CINAHL Headings. • Concept 5: • Risk Factors (explode): (MH “Risk factors+”).

3.2.3 Search strategy

The online databases US National Library of Medicine (PubMed), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Elsevier's Abstract and Citation database (SCOPUS) were searched through the UTAS library database search function. Five concepts (groups of terms relating to each concept) were established using the Medical Subject Headings (MeSH) and key words – Diabetes Mellitus, type 2: prediabetic state: hyperglycaemia AND risk factors: precipitating factors AND asymptomatic: undiagnosed AND surveys and questionnaires: health status indicators: risk assessment: screening; risk assessment tool AND aged: older adults: people over 60 years: young-old: seniors.

The search retrieved information for 1235 articles. After title scanning, 671 articles were selected as potentially relevant (subsequent titles to be added for updating the literature). Additionally, papers were identified through ancestral searches of bibliographies and cited research articles. Additional searches comprised hand searches and snowballing from references in articles already in hand, and via grey literature from government, non-government sources and policy documents relating to risk factors, screening and prevention and management of T2DM and precursor preDM.

3.2.4 Inclusion/exclusion criteria

Articles were included if they related to one of the following topics:

- Type 2 diabetes and prediabetes
    - Pathophysiology – all ages; specifically, in the older age group
    - Prevalence – all ages; specifically, in the older age group
    - Complications and increased risk for other medical conditions
- Screening Guidelines and policies
    - Screening interventions
    - Screening via medical practitioners
    - Screening via other health practitioners

    - Non-medical/non-health screening interventions
    - Screening type – opportunistic, targeted, population
    - Screening – specifically older age cohort
- Risk Assessment
    - Risk assessment tool prior to biomedical assessment
    - Assessment of known risks – biomedical
- Qualitative impacts on participation and outcome of screening
    - Socioeconomic
    - Perception of diabetes risk
    - Diabetes awareness, Health literacy
- Economic
    - Cost of screening
    - Cost of type 2 diabetes/prediabetes

Articles were excluded if they:

- pertained to non-multicultural populations
- were in a non-English language
- did not include risk assessment for the 60 -74-year age range
- had a participant mean age of less than 65 years
- pertained only to Type 1 diabetes, Gestational Diabetes Mellitus, LADA
- examined genetic factors only.

3.2.5 Article selection

The titles and key words section of the articles identified by the searches were examined, and those not on the topics for consideration were excluded. The abstracts of the remaining articles were read. Articles not based on the major inclusion criteria were excluded and any articles, which appeared potentially relevant, were kept for further examination.

The remaining articles were then examined fully (the whole text) for the specific topic relevance for which they would be used. The principles of *PRISMA* (Preferred Reporting Items for Systematic Review and Meta-Analysis) were used in determining the final content of the Literature Review. The PRISMA Flow Diagram (Figure 1) provides the visual representation of the decision-making procedure used to determine inclusion/exclusion of articles in this thesis.

3.2.6 Endnote compilation

Once the combined search was complete for each database the references were saved in a single master folder in Endnote.

Abstracts were further categorised within EndNote subheadings according to topic contribution for the Literature Review.

3.2.6.1 EndNote Keep Abstracts sub-categories

1. Pathophysiology of T2DM
2. T2DM prevalence
3. Models of T2DM
4. T2DM risk
5. Guidelines/policies for T2DM screening
6. T2DM risk assessment tools
7. T2DM medical screening
8. Screening in non-medical settings
9. Prevention T2DM via screening
10. T2DM screening for older individuals

11. Prevention preT2DM in older individuals

12. Qualitative elements in T2DM screening

13. T2DM awareness

14. T2DM risk perception

15. Socioeconomic impacts on screening

16. Cost of diabetes

17. Cost of screening

18. Other screening models

19. T2DM complications in older people

20. Multicultural community cohorts.

3.2.7 PRISMA flow diagram

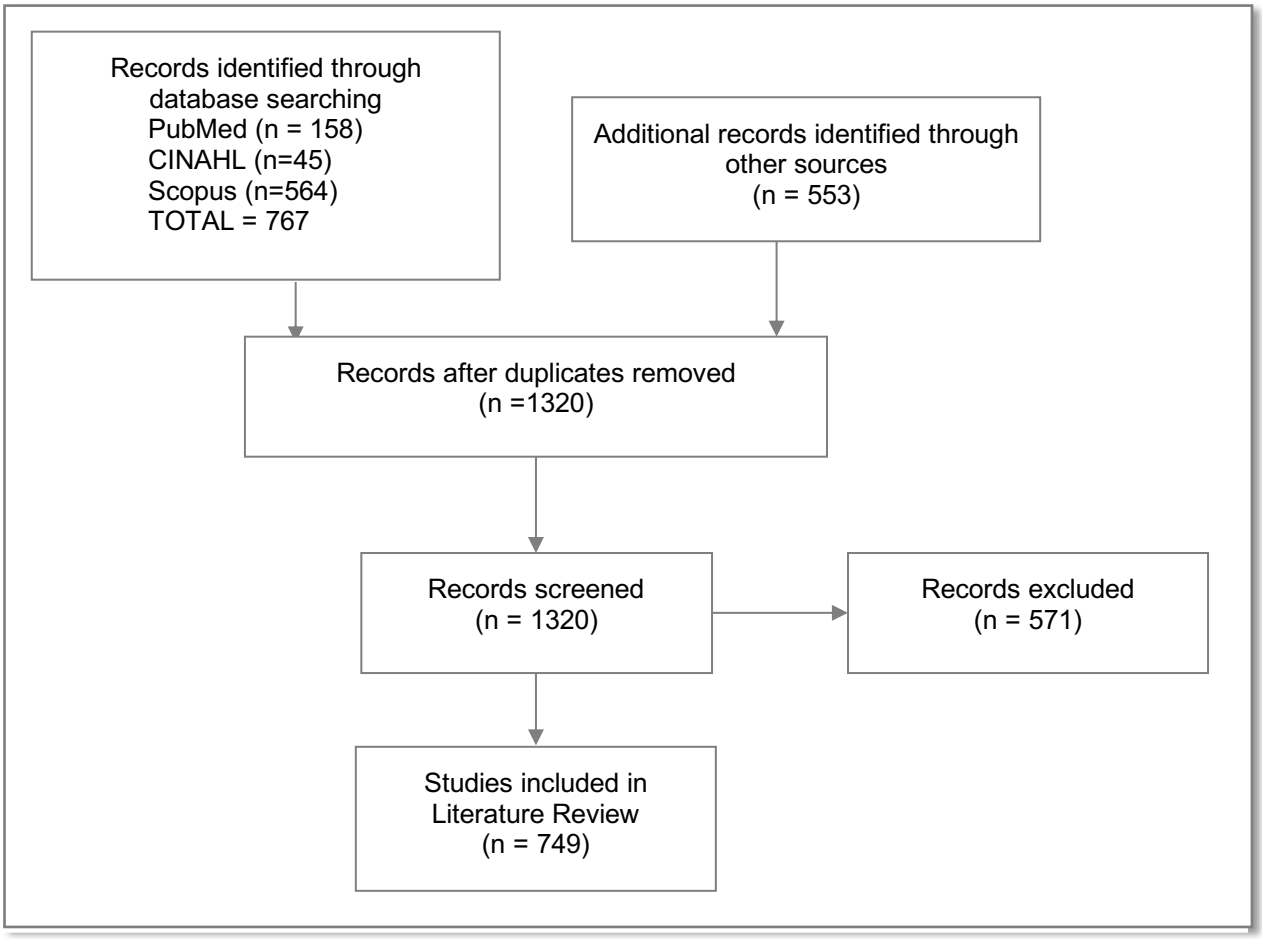


Figure 3.1 PRISMA Flow Diagram.

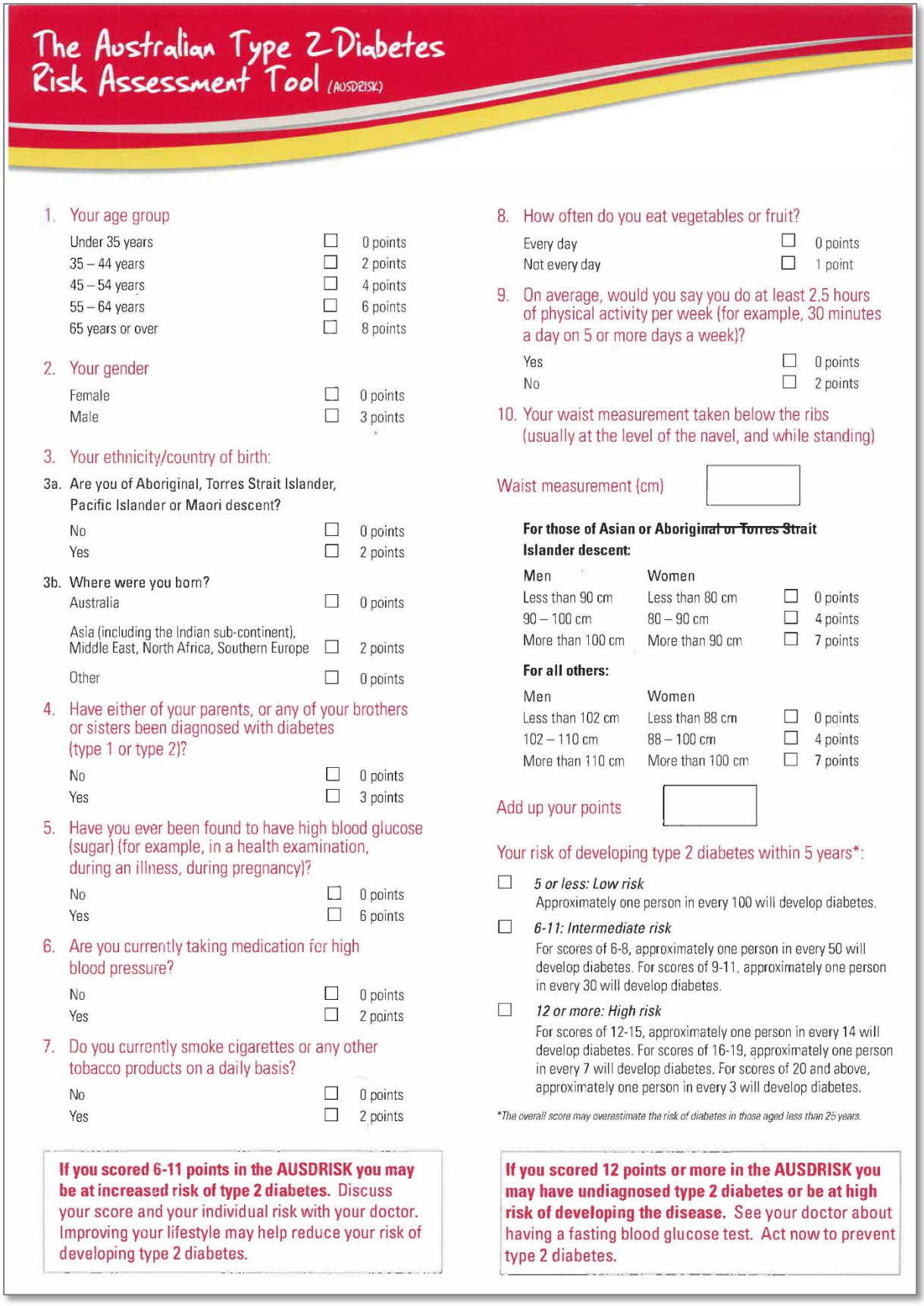
3.3 Data collection and analysis of results

3.3.1 *AUSDRISK* Assessment Tool (for information/instruction forms see appendices)

The *AUSDRISK* is a 10-item, validated questionnaire that estimates an individual's risk of progression to T2DM over a 5-year period (Appendix 1). The *AUSDRISK* comprises questions related to risk of developing T2DM based on age, gender, ethnicity, family history of diabetes, history of abnormal glucose metabolism, current hypertensive treatment, smoking status, physical activity, fruit and vegetable consumption and waist circumference. Each risk factor is apportioned a numerical score based on its impact on T2DM risk. The individual risk factor scores are added together to reach a total score. A total score of 12 points or more indicates the individual is at High Risk (HR). Within the HR category there are

3 levels progressing from HR1 (12-15 points) = approximately one person in every 14 will develop T2DM in 5 years; HR2 (16-19 points) = approximately one person in every 7 will develop T2DM in 5 years; HR3 (20 points or more) = approximately one person in every 3 will develop T2DM in 5 years. The *AUSDRISK* assessment tool provides an estimate of risk, not a diagnosis of T2DM. The purpose for using the *AUSDRISK* as the first step in a T2DM screening process, is for the *AUSDRISK* total score to first identify those individuals estimated to be at HR prior to implementing a biomedical assessment for confirmation/not of T2DM diagnosis or raised blood glucose levels but not at the level designated for T2DM. As such the *AUSDRISK* acts as a filter, to reduce the number of unnecessary blood tests (biomedical assessment) and target those individuals who, by their total *AUSDRISK* score, have shown there is a need for a biomedical assessment. This is particularly important as T2DM is a condition that has few specific symptoms to indicate a person's blood glucose level.

The *AUSDRISK* not only presents risk items with their risk score but also includes information (at the base of the pamphlet) regarding the individual's estimated level of risk and advice on the follow-up actions that the individual is recommended to complete. Those individuals scoring in the HR category are advised to see their doctor about having a fasting blood glucose test.



The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

1. Your age group

Under 35 years	☐	0 points
35 – 44 years	☐	2 points
45 – 54 years	☐	4 points
55 – 64 years	☐	6 points
65 years or over	☐	8 points

2. Your gender

Female	☐	0 points
Male	☐	3 points

3. Your ethnicity/country of birth:

3a. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?

No	☐	0 points
Yes	☐	2 points

3b. Where were you born?

Australia	☐	0 points
Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe	☐	2 points
Other	☐	0 points

4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)?

No	☐	0 points
Yes	☐	3 points

5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness, during pregnancy)?

No	☐	0 points
Yes	☐	6 points

6. Are you currently taking medication for high blood pressure?

No	☐	0 points
Yes	☐	2 points

7. Do you currently smoke cigarettes or any other tobacco products on a daily basis?

No	☐	0 points
Yes	☐	2 points

8. How often do you eat vegetables or fruit?

Every day	☐	0 points
Not every day	☐	1 point

9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?

Yes	☐	0 points
No	☐	2 points

10. Your waist measurement taken below the ribs (usually at the level of the navel, and while standing)

Waist measurement (cm) ☐

For those of Asian or Aboriginal ~~or Torres Strait~~ Islander descent:

Men	Women		
Less than 90 cm	Less than 80 cm	☐	0 points
90 – 100 cm	80 – 90 cm	☐	4 points
More than 100 cm	More than 90 cm	☐	7 points

For all others:

Men	Women		
Less than 102 cm	Less than 88 cm	☐	0 points
102 – 110 cm	88 – 100 cm	☐	4 points
More than 110 cm	More than 100 cm	☐	7 points

Add up your points ☐

Your risk of developing type 2 diabetes within 5 years*:

☐ *5 or less: Low risk*
Approximately one person in every 100 will develop diabetes.

☐ *6-11: Intermediate risk*
For scores of 6-8, approximately one person in every 50 will develop diabetes. For scores of 9-11, approximately one person in every 30 will develop diabetes.

☐ *12 or more: High risk*
For scores of 12-15, approximately one person in every 14 will develop diabetes. For scores of 16-19, approximately one person in every 7 will develop diabetes. For scores of 20 and above, approximately one person in every 3 will develop diabetes.

**The overall score may overestimate the risk of diabetes in those aged less than 25 years.*

If you scored 6-11 points in the AUSDRISK you may be at increased risk of type 2 diabetes. Discuss your score and your individual risk with your doctor. Improving your lifestyle may help reduce your risk of developing type 2 diabetes.

If you scored 12 points or more in the AUSDRISK you may have undiagnosed type 2 diabetes or be at high risk of developing the disease. See your doctor about having a fasting blood glucose test. Act now to prevent type 2 diabetes.

Figure 3.2 Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK).

3.3.1.1 AUSDRISK screening study introduction

This *AUSDRISK* screening study was conducted during a 6-month period from May to November 2014 in Tasmania, Australia.

Three settings were chosen to reflect a range of non-medical community settings in which the *AUSDRISK* might be implemented and outcomes assessed. Two settings were health-related and comprised the Direct recruitment component of the study – a public health community integrated care centre and 2 optometry clinics within a private health optometry practice. The other setting was non-health-related mail out specifically for individuals over the age of 60 years who were eligible for a Seniors Card (SC) (Australian Government, 2019b). Individuals may apply for a SC if they are aged over 60 years, are retired or working for less than 20 hours per week. It is not related to the aged pension. At the time of the study over 96,000 older Tasmanians had a SC. This number has increased to 106,000 in 2018–19 (Australian Government, 2019b). New and renewed SCs are mailed to the recipients. Mailouts to 500 individuals occur every 6 weeks. Three SC mailouts covered the Indirect recruitment component of this study. Details of the settings are provided in section 3.3.1.4 Phase 1 recruitment, settings and eligibility criteria.

3.3.1.2 Participating organisations – formal agreements

The *AUSDRISK* trial received approval from the organisations (see Appendix 2,) in which the trial was implemented. There were limitations imposed by each of the sites. All prospective participants were to be advised that participation was voluntary and their details and all details were kept confidential. Implementation of the *AUSDRISK* was required to be within the normal duties of the staff of the health services and therefore may not be possible during very busy times. The manager of the community healthcare centre gave permission for the *AUSDRISK* to be implemented for all new adult out-patients (18 years and over) as part of a new patient assessment over a 2- month period only. New patients under the age of 50 years were advised that they were welcome to complete an *AUSDRISK* but their scores would not

be used as part of the project. Similarly, the directors of the two optometry clinics agreed to a 2-month implementation of the *AUSDRISK* only if all adult clients (18 years and over) who were having a full vision assessment (1-hour with pupil dilatation) could be invited to participate. Those who were under the age of 50 were advised that their results would not be used in the project. Participation was voluntary. The manager of the Tasmanian State Government Seniors Bureau gave permission to include the *AUSDRISK* project documentation in 3 mail-outs (500 per mailout) of new or renewed SCs over a 6-month period (See Appendix 2 for project documentation).

3.3.1.3 Staff training

In the Community Health Centre (CHC) setting, Community Service Officers (CSOs) manage all the new patient admissions for the CHC. The CSO Team leader was designated and trained (training schedule see Appendix 2) to be the clinical/administrative coordinator of the *AUSDRISK* project. All CSOs were trained to introduce the *AUSDRISK*. On completion of the admission procedures and the *AUSDRISK,* the new patient progressed to their first treatment session. At a convenient point in the treatment session, the Allied Health Professional (AHP) reinforced the importance of knowing your diabetes risk status. If the patient had been assessed as HR, the AHP would briefly reinforce the importance of the patient attending their GP for biomedical assessment (Appendix 2).

In the optometry practices, the optometrists were trained to introduce the *AUSDRISK* as they considered it opportune to discuss the importance of patients knowing their T2DM risk in relation to eye health. The optometrists introduced the *AUSDRISK* at a time deemed suitable in the full eye assessment consultation (Appendix 2), and then followed the same process, as described for the CHC, for those assessed as HR. The optometrists explained that optometry assistants' duties did not include providing information in regard to eye health, and therefore it was not appropriate for them to be involved in the presentation of *AUSDRISK.*

Recruitment and data collection protocols (Appendix 3).

3.3.1.4 Phase 1 recruitment, settings and eligibility criteria

In all settings, participation was voluntary. There were 2 methods of recruitment. Direct recruitment (face-to-face) of 217 participants was conducted in two health care settings in Southern Tasmania: a community healthcare centre (public health) and two metropolitan optometry practices (private health). Indirect recruitment via 3 state-wide mailouts (500 per mail out) to 1500 older adults was achieved by utilizing the State Government statewide *Seniors Card* (SC) mail-out services.

Exclusion criteria for Direct recruitment of adult individuals via the health service settings were:

- a previous diagnosis of diabetes (all forms)
- cardiovascular diseases or neurologic diseases that would compromise the person's ability to participate in the study
- any admissions for community palliative care treatment at home and
- inability to reliably understand the English language, even with assistance.

Individuals aged under 50 years were invited to complete the *AUSDRISK* (as per service agreements with health services) but were advised that their results would not be included in the research project. The only exclusion criteria for those recruited via mailout was a diagnosis of any form of diabetes.

3.3.1.5 Direct recruitment process

Clinical admission staff introduced the *AUSDRISK* to new patients as an assessment of their risk for T2DM, not a diagnosis of T2DM. Advice was provided on the importance and advantages of being aware of their risk status for T2DM. Each patient was advised that completion of the *AUSDRISK* was part of a research study by the University of Tasmania and as such, participation was voluntary. The need for consent was explained prior to commencement of the *AUSDRISK*. The process for completing the *AUSDRISK* was explained and assistance was offered for completion (not content). Those who scored HR

were reminded that the score indicated their risk for T2DM (not diagnosis) and that the recommendation on the *AUSDRISK* was that they attend their GP for a biomedical assessment (blood test) to check their blood glucose (sugar) level.

Due to agreements with the health services, some new patients in the health services who completed an *AUSDRISK* were younger than 50 years. Health service staff advised these patients they would not be included in this study but should note the recommendations for their *AUSDRISK* score.

3.3.1.6 Indirect recruitment process via three Seniors Card mail-outs

With each mail-out, in addition to the SC, the recipients received an invitation (see Appendix 2) to self-assess their diabetes risk status; an *AUSDRISK*; an information/instruction/consent form providing written directions on completing the *AUSDRISK* (Appendix 2); and a reply-paid envelope to return documentation.

3.3.1.7 Phase 2 – high risk follow-up survey

High risk participants (from all recruitment settings) were invited to participate in a follow-up survey (by phone or email which ever they preferred) in 5-6 weeks to advise the researcher on the measures they had taken with reference to establishing their current blood glucose level. The 5-6 week timeline was chosen as being sufficient time for participants scoring HR to contact/not contact their GP (as per instruction on *AUSDRISK* Assessment Tool) for a biomedical assessment. Participation was voluntary and, if agreeing to participate in the follow-up survey, those at HR provided additional written consent, preferred contact details and returned all documentation in the reply-paid envelope. The survey comprised eight questions (in Appendix 3) relating to the HR participants' follow-up actions after completion of the *AUSDRISK* including their attendance/non-attendance for biomedical assessment; if attending, their general practitioner's actions and recommendations, and blood test results indicating their current glycaemic status. Those HR participants who chose to complete the survey online received an email with a direct link to the *Survey Monkey* format of the survey

(Appendix 3). Those who chose to complete the survey via a phone call had their responses recorded by the researcher who then transcribed the responses into the Survey Monkey format.

All responses were analysed via the Survey Monkey format. As part of the follow-up survey there was an opportunity for HR participants who chose to complete the follow-up survey by phone to comment on their prior awareness of *AUSDRISK,* and on the questions and related points score contained in the *AUSDRISK*.

3.3.1.8 High risk follow-up survey

Table 3.2 High risk follow-up survey questions

Survey questions	
Q1	Have you seen your GP about your HR *AUSDRISK* result? (Yes/No) If No, go to Q8
Q2	When you saw your GP, did you have blood tests to check if you had T2DM? (Y/N) If no go to Q6
Q3	If you had blood tests, did the results show you had T2DM? (Y/N) If No, go to Q5
Q4	If you were found to have T2DM on your blood tests, did the GP prescribe tablets to manage your T2DM? (Y/N)
Q5	Did the GP advise changes to your lifestyle? (Y/N)
Q6	If your blood tests showed no T2DM, did the results show pre-diabetes or high blood sugar? (Y; N; DK)
Q7	Did your GP discuss lifestyle changes to reduce your risk for developing T2DM in the future? (Y/N) End
Q8	Will you go and see your GP about your HR *AUSDRISK* result? (Y/N) End

.

3.3.2 Data collection

De-identified quantitative data were recorded from the information/consent forms and online survey forms (examples attached). De-identified qualitative data were compiled from paper-based standardised records of interview for the follow-up survey, and from paper-based records of the participating health professional and administrative staff.

The follow-up survey was presented in Survey Monkey format to HR participants who requested email as their preferred option for receiving the follow-up survey. The follow-up survey information collected from HR participants over the telephone was transcribed into the Survey Monkey format for analysis of all information received via the follow-up survey.

3.3.3 Statistical analysis

Descriptive data were entered into the STATA 12 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP), a data analysis and statistical software package and collated. For comparisons of groups, t-tests were used to compare continuous outcomes, and chi-squared tests for categorical outcomes. A *P* value of less than 0.05 was considered statistically significant. Interactions, such as those between gender/high risk category/GP attendance, were tested by using log-binomial regression (Poisson regression model) and included cross-product terms in the model.

The feasibility of implementing the *AUSDRISK* was assessed in Phase 1 by the uptake of the *AUSDRISK* achieved via the two recruitment methods (Direct/Indirect), and initial completion of the *AUSDRISK*, and in Phase 2, by comparing those assessed as High Risk who participated in the follow-up procedures, in comparison to those who did not.

The effectiveness of the *AUSDRISK* was determined by the predictive value of the HR scores on *AUSDRISK* for identifying participants with a T2DM result on biomedical assessment and will be covered in the following chapters.

3.3.4 Ethics

This study was supported and approved by all participating organisations and received Ethics Approval (H0013490) from the Human Research Ethics Committee (Tasmania) Network (Appendix 4). The Study received approval and funding from the virtual Tasmanian Academic Health Precinct Study (Appendix 5).

Chapter 4. Results Phase 1

4.1 Phase 1. Distribution and uptake of the AUSDRISK by older adults in 3 different community settings

4.1.1 Introduction

In the previous chapter the methodology and methods for this study were covered in detail. This chapter describes Phase 1 of the study which includes distribution of the *AUSDRISK* in three different community settings and uptake of *AUSDRISK* by older individuals residing in the community. The purpose of this part of the study was to identify older individuals at High Risk (HR) for T2DM and examine any differences in the *AUSDRISK* uptake between the settings and participants. First, it was essential to establish the baseline characteristics of each setting, the method of *AUSDRISK* distribution and the age-range, number and gender of individuals participating.

The *AUSDRISK* and the information/instruction/consent form was distributed in two health service settings over a 6-week period between May and November 2014 to new adult out-patients at the Clarence Integrated Care Centre (public health), and to adults over the age of 50 years having a full vision assessment at two optometry practices (private health). During the same period six-month period (May–November 2014) an *AUSDRISK* plus the information/instruction/consent form and a letter of invitation to participate in assessing their risk for T2DM was distributed to 1500 older adults aged 60 years and over, via three state-wide Seniors Card mail-outs (500 per mail-out). The Tasmanian Seniors Card Program is part of a State Government initiative, conducted by the Tasmanian Government Seniors Card Bureau, and jointly supported by private enterprise. Currently in Tasmania there are over 109,000 registered Seniors Card holders, supported by more than 600 businesses that offer a diverse range of discounts on products and services. It is available to all older individuals 60 years and over who are either not working more than 20 hours per week or retired. The older adults who completed an *AUSDRISK* in the healthcare settings formed the Direct Recruitment cohort. Those older adults who responded to the Seniors Card mail-out

by completing the *AUSDRISK* and returning the information/instruction/consent form to the researcher, formed the Indirect Recruitment cohort. All older participants who scored HR on the *AUSDRISK* were invited to take part in a follow-up survey (by phone or email according to their preference) to report their actions to the recommendation (for further action) that was linked to their HR score on the *AUSDRISK*. At the time of the research there were many older adults in Tasmania who did not have access to the internet. Providing them with 2 options was utilized to mitigate large participation bias of only having replies from those who had internet access.

The Phase 2 follow-up data is reported in Chapter 5.

4.2 Objectives

The objectives of this phase were to document: the findings on distribution, participation, and completion of the *AUSDRISK* tool across 3 community-based settings; the demographics of the older age cohort and their initial responses to participating in self-assessment of their T2DM risk by completing an *AUSDRISK*, and the number and gender of participants who scored HR on the *AUSDRISK* by their HR level (HR1, HR2, HR3) and recruitment method (Direct or Indirect).

4.3 Methods

Descriptive data were entered into the STATA 12 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP), a data analysis and statistical software package and collated. For comparisons of groups, a t-test was used to compare continuous outcomes, and a chi-squared test for categorical outcomes. A *P* value of less than 0.05 was considered statistically significant.

The feasibility of implementing the *AUSDRISK* was assessed in Phase 1 by first, the distribution of the *AUSDRISK* achieved via the two distribution methods, and secondly, the initial completion of the *AUSDRISK.*

4.4 Results

4.4.1 Settings and *AUSDRISK* distribution

During the trial period May–November 2014, the *AUSDRISK*, along with an instruction/information/ consent form, was distributed to 1717 older adults residing in the community. As per agreement with the health service recruitment centres (CICC and optometry), the research project was required to offer the *AUSDRISK* to all adults irrespective of age if they met all other requirements of the study.

At the Clarence Integrated Care Centre (CICC), 177 new adult out-patients were approached to participate in the study. Of those, 28 individuals had diabetes (type 1 or type 2) and were ineligible to participate in the study, 54 individuals declined participation, leaving 95 potential participants. Of these, 81 participants successfully completed the *AUSDRISK* and 14 participants/individuals commenced the *AUSDRISK* but did not successfully complete and were excluded from the study. There were 5 adults who successfully completed the *AUSDRISK* and scored HR who were aged under 50 years (2 x 40-50 years; 2x 30-40; 1x < 30). The initial participants who scored HR but were aged under 50 years were excluded from the HR analysis as they did not meet the age requirements of the study. This left 76 eligible participants from the CICC.

At the optometry practices, 40 adults were approached to participate in the study, and none refused participation. Thirteen of those approached had diabetes (type 2) and were ineligible to participate in the study, and of the remaining 27 individuals, 26 successfully completed the *AUSDRISK* and 1 commenced but did not complete the *AUSDRISK*. Within the group who successfully completed the *AUSDRISK* there were 2 adults (aged 49, 45 years) who scored HR but did not meet the age requirements of the study and were excluded from the HR analysis. This left 24 eligible participants from the optometry practices.

Three Seniors Card mail-outs were utilised to invite 1500 individuals aged 60 years and over to participate in the *AUSDRISK* study. The mail-out initiative achieved a balanced statewide

distribution – 51% South; 45 % North/North West; 4% East Coast which is broadly representative of the state's population. There were 293 responses received. Of these, 24 individuals reported diagnosed diabetes and were ineligible to participate in the study and 67 individuals declined participation. No participant failed to successfully complete the *AUSDRISK*. Thus 202 potential participants were Indirectly recruited.

After removal of ineligible participants, the number of potential participants was reduced to 1645 with 169 in the Direct Recruitment cohort and 1476 in the Indirect Recruitment cohort. Of those remaining, 121 individuals declined to complete the *AUSDRISK* (54 individuals in the Direct recruitment group and 67 in the Indirect mailout group) and there was no response from a total of 1207 individuals from the Seniors Card mail-out. The *AUSDRISK* was attempted by 317 eligible participants, however 15 directly recruited participants commenced the *AUSDRISK* but did not satisfactorily complete. Thus, leaving a final total of 302 *AUSDRISK* forms satisfactorily completed (Table 4.1).

Table 4.1 Participant recruitment by Settings by AUSDRISK completion

	Direct. CICC & Optom	**Indirect. Seniors' Card**	**Total**
Potential participants	217	1500	1717
Invitees diagnosed with diabetes	41	24	65
Ineligible due to age	7	0	7
Declined participation	54	67	121
No active response to invitation	0	1207	1207
Eligible participants who attempted *AUSDRISK*	115	202	317
Incomplete *AUSDRISK*	15	0	15
Final *AUSDRISK* completion	100	202	302

4.4.2 *AUSDRISK* results by recruitment settings

A final total of 302 (17.6%) participants formed the study group having completed an *AUSDRISK* with 100 (5.8%) directly recruited and 202 (11.8%) indirectly recruited.

The *AUSDRISK* results indicated that 136 individuals had scored in the High Risk category (12 points or more); 154 individuals scored in the Intermediate Risk category (6-11 points) and 12 adults scored in the Low Risk range category (5 points and under). Those who scored in the Intermediate Risk or Low Risk categories were not included in the remainder of this study which addressed only those who scored in the High Risk category. The final High Risk group of 136 individuals comprised 37/136 (27.2%) individuals directly recruited and 99/136 (72.8%) individuals indirectly recruited and formed the Study Group (Table 4.2).

Table 4.2 AUSDRISK results by Recruitment settings

	DIRECT	INDIRECT	TOTAL
***AUSDRISK* completion**	100	202	302
Study Group			
High Risk (HR) (≥12 points)	37	99	136
Intermediate Risk (IR) (6-11 points)	51	103	154
Low Risk (LR) (5 points or less)	12	0	12

4.4.3 HR participants by age range

The ages of the 136 HR participants ranged from 50–85 years with a mean age of 65.4 years and a standard deviation of 6.9. The age range for HR participants directly recruited was 50–85 years with a mean of 65.0 years. For those HR participants indirectly recruited the age range was 60–82 years with a mean of 65.5 years.

Increasing age is a major non-modifiable risk factor for T2DM. This is reflected on the *AUSDRISK* by the *AUSDRISK* points score for age increasing by 2 points for each age group, commencing at 0 points (under 35 years); 2 points (35–44 years); 4 points (45–54 years); 6 points (55–64 years) and 8 points (65 years or over). As the commencing age for

our older age cohort was fifty years, the first age range score was 4 points (50–54 years). The distribution of age ranges in the 136 participants who scored High Risk were; 4 participants (50–54 years); 59 participants (55–64 years) and 73 participants (65 years or over) (Table 4.3).

Table 4.3 Age-related (AUSDRISK points) by HR participants

Age related (*AUSDRISK* points)	**HR participants**
50–54 years (4 points)	4
55–64 years (6 points)	59
65 years or over (8 points)	73
TOTAL	136

Within the Direct recruitment group of 37 HR, 11 were aged 50-60 years, and 26 were aged 60+ years. Of the 11 aged 50-60 years, there were 4 x HR1; 4x HR2 and 3 x HR3. Within the full HR group of 136 (Direct and Indirect), 8.0% were aged between 50-59 years, and 92.0% were aged 60 years and over. Distribution of HR scores was 64 x HR1; 48 x HR2; 24 x HR3.

4.4.4 Distribution of high risk score

The distribution of individual HR scores for older adults in this study ranged from 12 to 31 points, with a mean of 16.2 points and standard deviation 3.7 points. The HR scores for the 37 directly recruited participants ranged from 12–24 points; mean = 16.7. For the 99 indirectly recruited participants the range was 12–31 points; mean = 16.0 points. For the total HR cohort, the mean score was 16.2 points.

4.4.5 Family history of diabetes

A family history of all forms of diabetes, that is an immediate family member or first/second degree blood relative (grandparent, parent, sibling) with diabetes, is another major non-modifiable risk factor in increasing an individual's risk for T2DM. In this study of 302 participants who completed the *AUSDRISK,* 56 individuals (across all settings) reported

having a family history of diabetes. Within the group scoring High Risk, 54 HR participants (across all settings) reported having a parent or sibling with diagnosed diabetes (Table 4.4).

Table 4.4 Family History by Participant and HR participant by recruitment setting

	Direct (%)	**Indirect (%)**	**Total (%)**
Family History by Total participants ≥50 years	18/100 (18.0%)	38/202 (18.9%)	56/302 (18.5%)
Family History by HR participants ≥50 years	16/37 (43.2%)	38/99 (38.4%)	54/136 (39.7%)

4.4.6 Participants scoring high-risk were distributed across all settings

Across all recruitment settings the distribution of *AUSDRISK* HR score levels (HR1–HR3) was consistent, that is in all settings the highest number of participants scored in the lowest HR level (HR1 12–15 points), and the smallest number of participants scored in the highest HR level (HR3 20 points and more).

The gender distribution between the Indirect and Direct recruited groups showed there were more HR males than HR females in the Indirect recruitment (SC) at all High Risk levels. Whereas in the Direct recruitment (CICC & OPTOM) HR group, the gender balance was the reverse, with more HR females than HR males at each HR level. However, when the results of the two distribution methods were combined there were more males and females at each of the HR score levels and final total (Table 4.5).

Table 4.5 HR participants by HR Levels by Gender by Recruitment settings

Settings by HR levels by Gender		HR1 12–15pts	HR2 16–19 pts	HR3 20pts+	TOTAL
Direct	Clarence Integrated Care Centre	9	11	7	27
	Gender	3M:6F	4M:7F	4M:3F	11M:16F
	Optometry practices	8	1	1	10
	Gender	1M:7F	1F	1F	1M:9F
Direct Combined	Combined CICC + Optom	17	12	8	37
	Gender	4M:13F	4M:8F	4M:4F	12M:25F
Indirect	Seniors' Card mail out	47	36	16	99
	Gender	32M:15F	22M:14F	10M:6F	64M:35F
TOTAL		64. 36M:28F. M = 56.3%	48. 26M:22F. M = 54.2%	24. 14M:10F. M = 58.3%	136. 76M:60F. M = 55.9%

4.4.7 High-risk by gender by recruitment setting (Direct vs Indirect)

A total of 37 HR participants (12 male and 25 female) were directly recruited from either Clarence Integrated Care Centre or the two optometry practices. There were 99 HR participants (64 males: 35 female) indirectly recruited via the Seniors' Card mail-out. The Direct recruitment strategy achieved 100 of 169 (59.2%) of its potentially eligible participants successfully completing an *AUSDRISK*. In comparison the Indirect recruitment strategy achieved only 202 of 1476 (13.7%) of its potential participants successfully completing an *AUSDRISK*. However, in terms of numbers of participants who scored HR, the Indirect recruitment strategy with 99 HR participants surpassed the Direct recruitment strategy which had recruited 37 HR participants.(Table 4.6)

Table 4.6 Direct vs Indirect Recruitment of HR participants by gender

Setting	Male (%)	Female (%)	Total (%)
Direct CICC and OPTOM	12 (32.4%)	25 (67.6%)	37 (27.2%)
Indirect SENIORS' CARD	64 (64.6%)	35 (35.4%)	99 (72.8%)
Total	76 (55.9%)	60 (44.1%)	136

Analysis of results from settings x gender distribution showed the gender distribution/balance in the Direct vs Indirect recruitment cohort was significantly different. Chi squared statistic is 10.258 *P* value = 0.00014. However, interpretation of these data is difficult as the gender ratio of those who declined to participate was unknown. In total 136 older individuals scored High Risk. Of those, 108/136 provided written consent to be contacted in 5-6 weeks to complete a follow-up survey to record their actions to seek a biomedical assessment to confirm their current blood glucose level (Appendix 3).

4.5 Summary of findings

Completion of Phase 1 showed both methods of distribution were feasible but uptake of the *AUSDRISK* was limited in health and non-health community settings. Of the 302 participants who completed the *AUSDRISK*, 136 (45.0 %) participants scored High Risk; 154 (51.0 %) participants scored Intermediate Risk, and 12 (4.0 %) participants scored as Low Risk.

The initial percentage uptake of *AUSDRISK* (response rate) in the Direct recruitment group (59.2%) was greater than the response rate in the Indirect recruitment Seniors' Card group (13.7%). This response differential is likely due to the method of initial recruitment with the Direct recruitment group who received a face-to-face presentation of the *AUSDRISK* by health service personnel. In addition, they were able to discuss any queries they had about the *AUSDRISK* and the benefit of knowing your diabetes risk. However, the face-to-face approach appeared not to have the same positive impact in recruitment via the optometry practices which provided the least number of participating clients in the recruitment phase. However, on completion of the *AUSDRISK* the Indirect recruitment via the Seniors' Card

mailout generated 99/136 (72.8%) HR participants in comparison with the Direct recruitment via health services which generated 37/136 (27.2%) HR participants. Potential reasons for these different response patterns will be considered in Chapter 6 Discussion.

Participants who scored High Risk were identified in all three recruitment settings. The distribution of *AUSDRISK* scores was consistent through all HR levels with the greatest number of participants scoring in the lowest HR level (HR1 = 12–15 points) and the least number scoring in the highest High Risk level (HR3 = 20 points or more). This result was consistent across all settings.

In the total Indirect recruited cohort, there were equal numbers of females and males (101 males and 101 females) who were eligible to participate. In the total Direct recruited cohort, there were twice as many females as males (68 females and 32 males) who were eligible to participate. However, in the HR cohort there were more males than females in total and at each of the HR levels (76 males and 60 females). The potential reasons for these differences will be discussed in the Chapter 6.

Participants with a family history of diabetes were identified in all settings. In the full study cohort, 18.2 per cent had a family history of diabetes. In the HR cohort, the percentage of those with a family history was 39.7 percent.

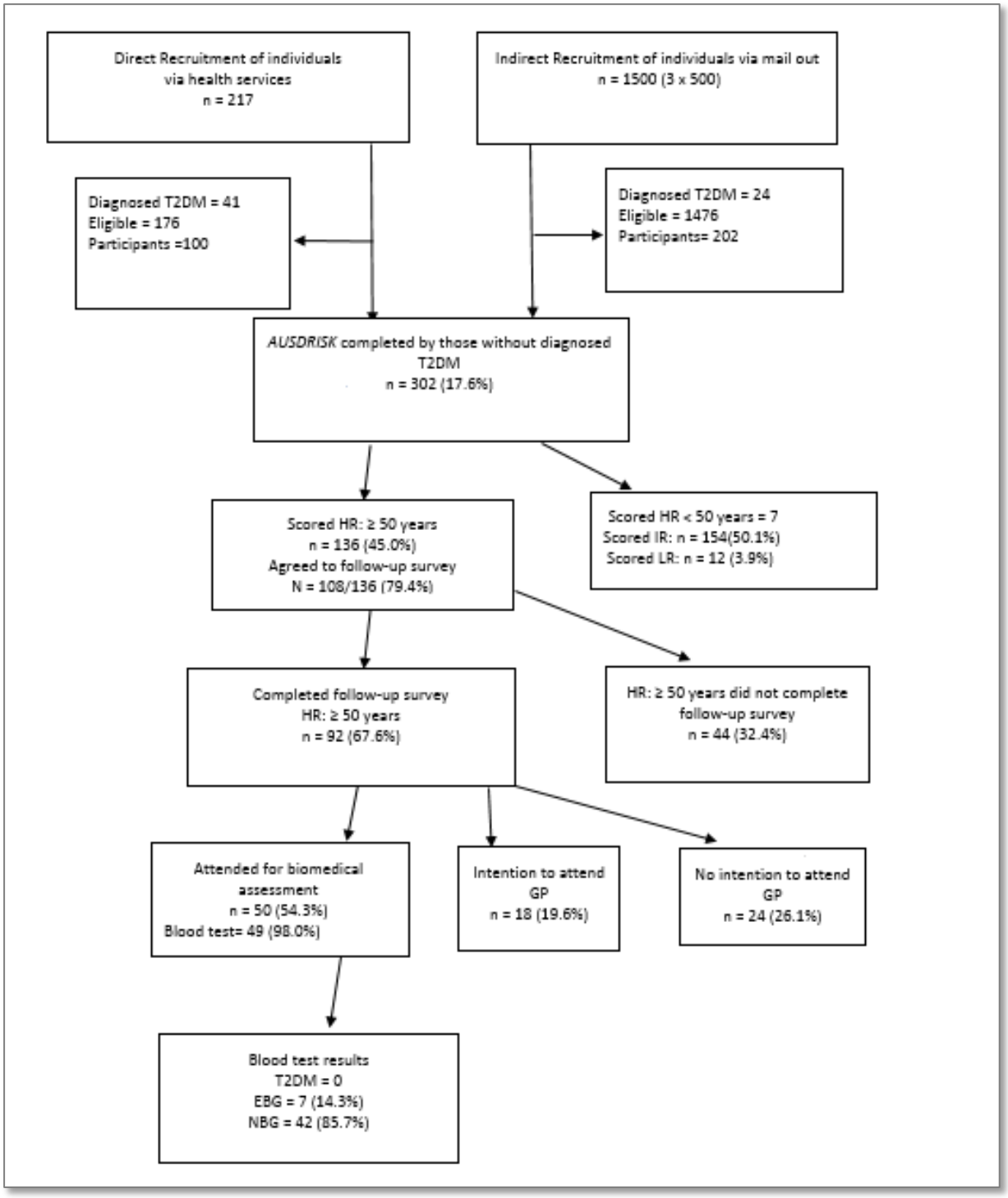


Figure 4.1 AUSDRISK Distribution, participation and T2DM risk profiles.

Chapter 5. Results Phase 2

5.1 Major finding

AUSDRISK had zero predictive validity for T2DM in HR older age cohort.

The major finding in this study of screening for T2DM in older-age participants was that the *AUSDRISK* HR scores had no predictive value for T2DM (positive predictive value = 0). Elevated blood glucose (EBG) levels were found across all HR levels (HR1 = 10.0% (2/20), HR2 = 17.6% (3/18), and HR3 16.7% (2/12). There was no association between the older-age participants' HR score levels on the *AUSDRISK* and the diagnosis of EBG. Those who were biomedically assessed as having EBG had a risk score that was, on average, only 0.95 units higher (P=0.50) than those at HR who were biomedically assessed as normoglycaemic.

This major finding begs the question that if the *AUSDRISK* is not effective in identifying T2DM in older individuals, what is the purpose of addressing whether it is feasible to distribute and acceptable to complete an *AUSDRISK* for the purpose of case finding for T2DM. However, there were additional findings that influenced participation which are applicable for promoting T2DM literacy, health promotion and participation in future T2DM screening for the older age cohort. These findings will be addressed via the stated objectives of the study.

5.2 Introduction to Chapter 5

The primary purpose of this component of the study was to discover if the *AUSDRISK* predicted whether older individuals, assessed as HR, had T2DM or preDM. In order to determine this outcome, the older HR individual needed to attend their GP regarding their HR score and for the GP to order a blood test to check their glycaemic status. This chapter covers the results of those participants assessed as High Risk (HR) for T2DM on the *AUSDRISK* who completed a follow-up survey reporting on whether they did or did not attend their GP for a blood test to confirm their blood glucose status (Refer Chapter 3 Methodology)

Section 3.3.1.7 Phase 2 – high risk follow-up survey). The study also aimed to discover the actions of their GPs in determining the individuals' blood glucose status. For those HR participants who attended their GP, the information in this chapter includes their GP's actions in determining the individual's current glycaemic status; each HR participant's blood test result and the GPs' directions to the HR participants subsequent to the blood test result – all this information was reported by the HR participant. In addition, the HR participants who completed the survey over the phone, had the opportunity (if they wished) to comment on their experience of completing an *AUSDRISK*, including the *AUSDRISK* questions, and provide their reaction to participating in this T2DM screening study generally. All analyses in Phase 1 and Phase 2 were pre-specified.

5.3 Objectives (in sequence of occurrence)

The first objective of Phase 2 was to record and compare the number and details of HR participants who completed the follow-up survey, with those who did not.

The second objective was to record the number and details of HR participants who completed the full screening sequence and compare these findings with those HR participants who did not.

The third objective was to record the results of the blood test (as reported by the HR participants) and determine the predictive value of the *AUSDRISK* HR score level in relation to the HR participants' glycaemic results.

The fourth objective was to record the GPs' actions on being advised by the participants of their HR *AUSDRISK* score (Did the GP order a blood test, or not?) and to record the GPs' directions (as reported by HR participants) to the HR participants following their blood test results.

The fifth objective was to record the free-text information provided by the HR participants via the follow up survey and a semi structured interview (using the follow-up survey format) for

those who completed the survey via phone. HR participants were invited to report their knowledge of the *AUSDRISK*, their knowledge, attitudes and beliefs towardsT2DM and risk for T2DM, and their response to receiving their blood test results. This qualitative information was sought to complement/enhance the quantitative results and provide comprehensive direction for planning future studies on T2DM screening for older adults.

5.4 Methods

The follow-up survey (available 3.3.1.8 High risk follow-up survey) provided single word responses (Yes, No, Don't Know) to the survey questions which included GPs' actions in response to participants' *AUSDRISK* HR score and recommendation for a biomedical assessment of their current glycaemic status; blood test results and GP recommendations following the blood test result was available. The follow-up survey was presented online in Survey Monkey format. An email containing a link to the survey was sent to HR participants who requested email as their preferred option for completing the follow-up survey. The follow-up survey information collected from HR participants whose preferred option for completion of the survey was via telephone, was written (by the researcher) on the paper form of the survey and transcribed into the Survey Monkey format for analysis of all quantitative information received.

The qualitative data on HR participants' knowledge and beliefs about T2DM and their reaction to being advised of their biomedical assessment results was collected from those HR participants who completed the survey via telephone. Their responses were recorded on paper survey forms and transferred to an Excel spreadsheet.

5.5 Statistical analysis

Descriptive data (quantitative) were entered the *STATA 12,* a data analysis and statistical software package and collated. For comparisons of groups, t-tests were used to compare continuous outcomes, and chi-square test for categorical outcomes. A *P* value of less than 0.05 was considered statistically significant. Interactions, such as those between gender/high

risk level/GP attendance, were tested by using log-binomial regression (Poisson regression model) and included cross-product terms in the model.

The feasibility of implementing the *AUSDRISK* was assessed in Phase 2, by comparing those assessed as High Risk who participated in the follow-up procedures, in comparison to those who did not. The effectiveness of the *AUSDRISK* was determined by the predictive value of the HR scores on *AUSDRISK* for identifying participants with a T2DM result on biomedical assessment**.**

Due to the small number of free-text comments, no attempt at formal analysis of these was made, but a narrative approach was employed as per the methods of Fetters et al.(2013), allowing patterns to emerge from certain groups. These are elucidated in section 5.10.

5.6 Results of follow-up study

5.6.1 Phase 2 follow-up survey

The screening results of this older age cohort (mean age 65.5 years) showed that 136 individuals (76 males and 60 females) scored High Risk. Of those HR individuals, 79.4% (108/136) being 66 males and 42 females provided written consent to complete a follow-up survey in 5-6 weeks following completion of the *AUSDRISK*. When the 108 HR participants who had agreed were contacted by either email or phone (by the researcher) only 92 actually agreed to complete the survey. Overall, 92 of the 136 HR participants (56 males and 36 females) completed the follow-up survey, and 44 (20 males and 24 females) did not.

5.6.2 Details of HR participants who completed/not completed the follow-up survey

Of the 92 HR participants who completed the follow-up survey there were 11 HR participants (3 males and 8 females) directly recruited (CICC and optometry clinics), and 81 HR participants (53 males and 28 females) were indirectly recruited (Seniors Card mailout).

Within the Direct recruited group there were 3 HR participants (1 male:2 female) recruited via optometry clinics and 8 HR participants recruited via CICC (2 males:6 female).

The distribution of HR score levels for the 92 HR participants who completed the follow-up survey was 42 HR1 (45.6%) participants (25 males:17 female); 32 HR2 (34.8%) participants (20 males: 12 female) and 18 HR3 (19.6%) participants (11 males :7 female). In this group of 92 HR participants 44.6% (25 males:16 female) had a family history of diabetes and 55.4% (31 males:20 female) did not. (Table 5.1).

Table 5.1 Details of HR participants who completed the Follow-up survey

	Male	**Female**	**Total**
Total	56	36	92
Recruitment			
Direct	3	8	11
Indirect	53	28	81
High Risk Levels			
HR1 12-15	25	17	42
HR2 16-19	20	12	32
HR3 >=20	11	7	18
Family History			
No	31	20	51
Yes	25	16	41

5.6.3 Analysis of completed follow-up study

Comparisons between the HR participants who completed or did not complete the follow-up survey were analysed with relation to participants' recruitment setting; age; gender; HR level; and family history.

5.6.3.1 Completion/non-completion follow-up survey by recruitment setting

The follow-up survey was completed by 92 participants who scored HR. Of the 44 HR participants who declined to participate in the follow-up survey 26 HR participants had been directly recruited, and 18 HR participants had been indirectly recruited. There were

significant differences between the Direct and Indirect recruitment in terms of proportion of HR participants completing/not completing the follow-up survey. χ^2= 33.4, *P* = <.00001. (Table 5.2), with those in the Indirect recruitment group more likely to complete the follow-up survey.

5.6.3.2 Completion/non-completion follow-up survey by age

The 92 HR participants (56 males: 36 female) who completed the follow-up survey had a mean age of 65.5 years (SD 6.1). The 44 HR (20 males: 24 female) who did not complete the follow-up survey had a mean age 65.1 years (SD 8.5). There was no significant difference in age between the two groups = 0.62 (t-test) n.s (Table 5.2).

5.6.3.3 Completion/non-completion follow-up survey by gender

There were no significant differences in male/female gender distribution of 56 males and 36 females who completed in the follow-up survey, compared to the 20 males and 24 females who did not complete the follow-up survey χ^2= 2.87. *P*=0.09 n.s (Table 5.2).

5.6.3.4 Completion/non-completion follow-up survey by HR levels

The range of HR score levels of the 92 HR participants who completed the follow-up survey comprised 42 HR1; 32 HR2 and 18 HR3. The range of HR score levels of the 44 who did not complete the follow-up survey comprised 20 HR1, 18 HR2 and 6 HR3.

There was no significant difference between the distribution of High Risk score levels in participation or non-participation in the follow-up survey (Table 5.2).

Table 5.2 Analysis of Completed Follow-up Study

	Completed survey No (%)	Completed survey Yes (%)	Total	
	44 (32.4%)	92 (67.6%)	136	
Gender				χ^2test = 2.8688 p= 0.09 n.s
Male	20 (26.3%)	56 (73.7%)	76	
Female	24 (40.0%)	36 (60.0%)	60	
Age				
Mean (SD)	65.1 (8.5)	65.5 (6.1)	65.4 (6.9)	*P*= 0.62 (t-test) n.s
Recruitment				χ^2= 33.4 significant p < .00001
Direct	26 (70.3%)	11 (29.7%)	37	
Indirect	18 (18.2%)	81 (81.8%)	99	
High Risk Category				χ^2= 0.59 n.s
HR1 12-1	20 (32.3%)	42 (67.7%)	62	
HR2 16-19	18 (36.0%)	32 (64.0%)	50	
HR3 >=20	6 (25.0%)	18 (75.0%)	24	

5.6.3.5 Completion/non-completion follow-up survey by family history

Information regarding a family history of diabetes was reported by 134/136 HR participants in Phase 1. Of the 92 HR individuals who completed the follow-up survey, 41 HR participants reported having a family history of diabetes and 51 HR participants either did not (49) or had not reported (2) having a family history. Of the 44 HR participants who did not complete the follow-up survey, 13 reported having a family history, and 31 did not have a family history. There was no significant difference (*P*=0.09) between completion/non-completion of the follow-up survey and the presence or absence of a family history of diabetes. (Table 5.3).

Table 5.3 Completed Follow-up survey by Family History

Family History	Completed Survey No	Completed Survey Yes	Total	$\chi 2 = 0.09$ n.s
No	31	51	82	
Yes	13	41	54	

5.7 Results of GP attendance/non-attendance by HR participants

Individuals who score High Risk on the *AUSDRISK* tool, that is, score 12 points or more, are advised, via the *AUSDRISK*, "to attend their GP for a fasting blood glucose test as they may have undiagnosed type 2 diabetes or be at high risk of developing the disease" (as per quote on the *AUSDRISK*).

5.7.1 GP attendance

Of the 92 HR participants who completed the Phase 2 follow-up survey, 54.3% (50/92, 27 males and 23 females) subsequently attended their GP for a blood test of their glycaemic status and 45.7% (42/92 29 males and 13 females) had not seen their GP by the time the follow-up survey was conducted 5-6 weeks after their completion of the *AUSDRISK*. Of those who had not attended their GP for a biomedical assessment, 19.6% (18/92) stated they planned to request blood tests when they had their regular annual or bi-annual appointment with their GP. Therefore, at the time of the follow-up survey 73.9% (68/92) HR participants had attended, or had stated an intention to attend their GP, and the remaining 26.1% (42/92) had not indicated an intention to see their GP about their HR score.

5.7.2 Attended GP by age

Of the 92 HR individuals who completed the follow-up survey, 50/92 HR (27male: 23 female) with a mean age of 65.1 years (SD 6.0) had attended their GP, and 42/92HR (29 male: 13 female) mean age 65.9 years (SD 6.2) had not attended their GP within a 5-6-week period when the follow-up survey was implemented. There was no significant difference in age between the attenders/non-attenders P=0.54 (t-test)n.s (Table 5.4).

5.7.3 Attended GP by gender

Of the 92 HR individuals who completed the follow-up survey, 54.3% (50/92) 27 males and 23 females had attended their GP, and 45.7% (42/92) 29 males and 13 females, had not attended. There was no significant difference in male/female attendance or non-attendance at GP (*P*=0.14) indicating that gender did not have a significant impact on the frequency of GP attendances or non-attendances for a biomedical assessment of HR participants' glycaemic status. χ^2 = 0.14 n.s (Table 5.4).

5.7.4 Attended GP by high risk level

The distribution of HR levels of the 50 HR individuals who attended their GP comprised 20 HR1 (13 males and 7 females); 18 HR2 (9 males and 9 females) and 12 HR3 (5 males and 7 females). The distribution of HR levels of the 44 who did not complete the follow-up survey comprised 22 HR1 (12 males and 10 females); 14 HR2 (11 males and 3 females); 6 HR3 (6 males and 0 females).

The participants' HR level did not influence attendance or non-attendance at the GP χ^2 = 0.38 n.s (Table 5.4).

5.7.5 Attended GP by family history

Of the 50 HR who had attended their GP, 25 HR individuals reported having a family history of diabetes and 25 individuals did not or had not reported it. Of the 42 HR who had not attended their GP, 16/42 reported having a family history whereas 26/42 did not have a family history. There was no significant difference in presence or absence of a family history in attending a GP for a biomedical assessment χ^2 = 0.18 n.s (Table 5.4).

5.7.6 Attended GP by Direct/Indirect recruitment

Of the 92 HR participants who completed the follow-up survey, there were 11 HR (3 males and 8 females) directly recruited via health services (CICC and optometry) and 81 HR (53 males and 28 females) indirectly recruited via Seniors Card mail out. Of the 11 HR directly

recruited, 7 HR participants (7 x CICC: 0 x optometry) had attended their GP and 4 HR participants had not. Of the 81 HR participants indirectly recruited, 43 HR had attended their GP and 38 HR had not attended. There was no significant difference in percentage of attenders vs non-attenders within each Direct and Indirect recruitment setting $\chi^2 = 0.51$ n.s and no significant difference within each of the three recruitment settings and GP attendance $\chi^2 = 0.33$ n.s (Table 5.4).

Table 5.4 HR participants by GP attendance

	Completed survey No	Completed survey Yes	Total	*P*-value
Total	42	50	92	
Age				
Mean (SD)	65.9 (6.2)	65.1 (6.0)	65.5 (6.1)	*P*=0.54 (t-test)n.s
Gender				χ^2 = 0.14 n.s
Male	29	27	56	
Female	13	23	36	
High Risk Category				χ^2 = 0.38 n.s
HR1 12-15	22	20	42	
HR2 16-19	14	18	32	
HR3 >=20	6	12	18	
Family History				χ^2 = 0.18 n.s
No	26	25	51	
Yes	16	25	41	
Recruitment				χ^2 = 0.51 n.s
Direct	4	7	11	
Indirect	38	43	81	
Recruitment settings				χ^2 = 0.33 n.s
CICC	3	7	10	
OPSM	1	0	1	
Seniors Card	38	43	81	

5.7.7 GP attendance by gender by high risk score level

There was a significant interaction between gender, HR score and GP attendance (test for interaction *P*=0.03). All interactions were determined by the Poisson regression method. The HR score level did not influence the behaviour of males to see their GPs (*P*=0.67), whereas for females, those with higher scores were more likely to attend their GP (test for trend *P*=0.002) with 100% GP attendance of females with a HR3 score level. (Table 5.5, Table 5.6).

5.7.7.1 GP attendance by HR males

Analysis of the association between males in different HR levels attending their GP demonstrated that the HR risk score level for males was not associated with whether they attended their GP (*P*= 0.727) (Table 5.5).

Table 5.5 GP attendance by male HR participants by HR score level

	GP attendance No	**GP attendance Yes**	**Total**	**P-value**
Total	29	27	56	
High Risk Category				
HR1 12-15	12	13	25	reference
HR2 16-19	11	9	20	0.647
HR3 >=20	6	5	11	0.727

5.7.7.2 GP attendance by HR females

Analysis of the association between females in different HR levels attending their GP demonstrated that there was a significant difference (*P*=0.002) between females in the HR3 level who were significantly more likely to attend their GP compared to females in the HR1 level. There was no significant difference between females in HR2 and HR1 levels (Table 5.6).

Table 5.6 GP attendance by female HR participants by HR level

	GP attendance No	**GP attendance Yes**	**Total**	***P*-value**
Total	13	23	36	
High Risk Category				
HR1 12-15	10	8	18	reference
HR2 16-19	3	8	11	0.131
HR3 >=20	0	7	7	0.002

5.8 Conclusions from HR participant biomedical assessment results

In 98% cases (49/50) of HR individuals presenting for biomedical assessment, the GP ordered a blood test (unspecified by most respondents) and in 70% cases the GP also provided lifestyle change advice (improved nutrition and increased exercise). One male participant (HR1) did not receive a blood glucose test, but did receive lifestyle modification advice.

Results of biomedical assessment showed that no individuals assessed as HR on the *AUSDRISK* tool were diagnosed with T2DM; 14.3% HR individuals (7/49) were advised by their GP that their blood glucose level was elevated (elevated blood glucose, EBG) (5.5-6.9 mmol/L) above the normal range, but not in the diabetic range (7 or above mmol/L) and 85.7% HR individuals (42/49) were advised that their blood glucose level was in the normal range (below 5.5 mmol/L), i.e. normoglycaemic (NG) at time of testing (Table 5.7).

There was no association between the HR score level on the *AUSDRISK* and the diagnosis of EBG χ^2 = 0.52 *P* = 0.77 n.s. Those HR participants who were biomedically assessed as having EBG had a risk score that was on average only 0.95 units higher (*P*=0.50) than those at HR who were biomedically assessed as normoglycaemic.

The *AUSDRISK* risk scores of the 7 HR individuals diagnosed with EBG, were distributed across all HR levels– 2 x HR1; 3 x HR2 and 2 x HR3 (Table 5.7). There was no interaction between risk score level, gender and EBG result (*P*=0.48). There was no statistical association between type of screening recruitment (Direct/Indirect), and risk score level (*P*=0.37). There was no statistical association between HR score levels (HR1:HR2:HR3) and the resultant glycaemic status on biomedical assessment (*P*=0.77). However, with small numbers of participants, the ability to draw specific statistical inferences is reduced.

Table 5.7 HR participant biomedical assessment results (49/50)*

	Gender		Biomedical assessment results (%) x gender		
Glycaemic status	Male	Female	EBG	NBG	EBG
HR1 = 20/49	13*	7	2 (1M: 1F)	18 (12M: 6F)	10.0%
HR2 = 17/49	9	8	3 (2M; 1F)	14 (7M: 7F)	17.6%
HR3 = 12/49	5	7	2 (2F)	10 (5M: 5F)	16.7%
Total. HR = 49 (27M: 22F)	27	22	7 (3M: 4F)	42 24M: 18F)	14.3%

Note – No optometry participants attended for biomedical assessment.

Note – *GP chose not to order blood test for one male (HR1).

EBG = Elevated Blood Glucose (pre-diabetes).

NBG = Normal Blood Glucose levels (normoglycaemia).

HR1 – 2 EBG = 1 Male 63 years; 1 Female 75 years.

HR2 – 3 EBG = 1 Male 67 years, 1 Male 76 years; 1 Female 60 years.

HR3 – 2 EBG = 1 Female 60 years; 1 Female 70 years.

5.9 HR participants' reports of GP advice following blood test results

Seven (7) HR individuals reported that their GP had advised them that they had elevated blood glucose but not in the diabetes range. However, as their blood glucose level was above the normal range, their blood glucose levels would be regularly monitored. They were also advised to make lifestyle changes (increase physical activity, eat a healthy diet and, if necessary, lose weight) to reduce their elevated blood glucose levels and reduce their risk for T2DM. No medication to facilitate reduction in blood glucose level was prescribed by their GPs for any individual having an EBG level. The 42 HR participants assessed as normoglycaemic were advised of this result. When asked by the researcher if they were advised to have regular blood glucose tests, all individually reported that their GP had not advised them that they should continue to have regular blood glucose testing. That is not to

say that GPs did not advise regular blood glucose monitoring but rather that the HR participants had no recollection of this. Of those assessed as normoglycaemic, 70.0% reported they were given lifestyle advice (improved nutrition and increase physical activity).

It is acknowledged that the information gathered regarding GP behaviour was necessarily second hand, and therefore, subject to inaccuracies. However, the information reflected the HR participants' comprehension of the GP information and directions presented.

5.10 HR participants comments and responses within the follow-up survey

As part of the follow-up survey, HR participants who completed the survey via phone were given the opportunity to provide comments on the *AUSDRISK* and its questions in addition to providing responses (Yes, No or Don't Know) to the specific questions on the follow-up survey. A total of 92 participants completed the follow-up survey. Of that total, 49 HR participants provided comment additional to their follow-up survey responses. By the time the follow-up survey was implemented 50 (50/92) HR participants had attended their GP. Of those 22 provided additional comments relating to the GP attendance and biomedical assessment. Additional comments were also received from 10 HR participants who had not seen their GP within the 5-6 week timeframe after *AUSDRISK* completion but reported at that time they intended to do so. In addition, 17 HR participants who chose not to attend their GP provided additional comment for their decision. There were 43 HR participants who indicated their actions for GP attendance/nonattendance by completing the follow-up survey but did not provide additional comment. Of those, 23 had attended their GP; 9 reported that they planned to attend their GP; 6 had chosen not to attend their GP and 5 HR participants did not respond (Table 5.8).

Table 5.8 HR participant responses/no responses within follow-up survey

	Comments - Yes	Comments - No	Total
Attended GP	22	23	45
Intention to attend GP	10	9	19
No intention to attend GP	17	6	23
No response		5	5
TOTAL	49	43	92

Due to the small number of free-text comments, no attempt at formal analysis of these was made, but a narrative inquiry was employed as a tool for allowing patterns to emerge from certain groups as per the methods of Fetters et al., (2013).

5.10.1 Comments made by HR participants who assessed as elevated blood glucose (EBG)

The seven HR participants who were biomedically assessed as having elevated blood glucose levels provided comments in relation to being advised of their current blood glucose status.

Comments from 2 male HR participants (Table 5.9) with EBG indicated that they and their GP were aware of their high risk status prior to completing the *AUSDRISK* and both HR participants had already made lifestyle changes, but remained at high risk. Comments from four of the other participants with EBG appeared to indicate that their *AUSDRISK* score triggered the first occasion their GP had ordered a blood glucose test and they were recommended to implement lifestyle changes (increase physical activity; follow a healthy diet and weight reduction if required) to reduce their risk for T2DM. None of these HR participants provided detail as to the implementation methods to achieve these goals. The female HR participant with rheumatoid arthritis voiced her concern at being unable to increase her physical activity. One female participant aged 75 years who scored HR1 reported that her GP had ordered an Oral Glucose Tolerance Test (OGTT). This may suggest that she had

had an FPG or HbA1c test initially (which she did not report) which was inconclusive, and the GP subsequently ordered an OGTT as a confirmatory test (Table 5.9). All HR participants with an EBG result were advised that their GPs would ensure they had regular blood glucose tests. No HR participant with EBG was referred to a diabetes prevention program nor to a Credentialed Diabetes Educator for diabetes education.

Table 5.9 Responses by 7 HR participants assessed as having Elevated Blood Glucose

HR participants/age/HR score	Comments
Male, 63 years, score HR1	"My GP said my blood sugar was up a bit. He'd keep an eye on it. I have to exercise more and be careful what I eat"
Female, 75 years, score HR1	"My GP said my blood sugar was up a bit. He ordered a test where you must drink a horrible sugary drink and then sit around for ages and they keep taking more blood tests. He said he would keep an eye on the situation".
Male, 76 years, score HR2	"Some time ago my blood sugar was a bit highish. My GP put me on Metformin. I lost 10 kg weight. So, the GP stopped Metformin. My blood sugars are now OK. I eat healthy things now".
Male, 67 years, score HR2	"I have borderline diabetes. My GP is aware of this and I have regular blood tests. Some of my family have diabetes".
Female, 60 years, score HR2	"I'm not surprised that my blood sugar is up a bit. I need to lose weight" (notes on the data collection form indicated no FH; age 6 points; therefore 12 points from other risk factors).
Female, 70 years, score HR3	"I have rheumatoid arthritis. My GP said my blood sugar was high. He said I should eat healthily and get more exercise. That's difficult with rheumatoid arthritis. He didn't give me any medication for the high blood sugar".
Female, 60 years, score HR3	" My GP recommended lifestyle changes – increase physical activity, improve nutrition and lose weight".

5.10.2 Comments from HR3 participants who were assessed as normoglycaemic

Of the 12 HR3 participants who had a biomedical assessment, 2 were assessed as having EBG and 10 were assessed as normoglycaemic. Examples of comments from those assessed as normoglycaemic would suggest that their GP had already recognised their high risk for T2DM prior to completion of an *AUSDRISK*. Two male HR3 participants* indicated they had implemented lifestyle changes or already lead a physically active lifestyle, but their

risk remained high (HR3) for T2DM. Five HR3 participants had a family history of diabetes and by their comments acknowledged the impact this (FH) would have on their overall risk for T2DM (Table 5.10).

Table 5.10 HR3 Participants who were assessed as normoglycaemic

HR3 participants assessed as Normoglycaemic	Comments
***Male, 63 years, score 20**	" I have regular blood tests because members of my family have type 2 diabetes. I walk for 30 minutes every day. I do a lot of gardening. It's on a steep slope. I don't eat junk food. I take tablets for depression and helping me to sleep"
Male, 66 years, score 21	"I'm not surprised that I scored high risk because my 2 brothers have type 2 diabetes".
Female, 73 years, score 22	" I have blood tests every 6 months to monitor cancer and high blood sugar levels. My sister has insulin for her diabetes".
Female, 60 years, Score 22	"Some of my family have diabetes. I saw the GP, but he didn't say anything about changing my lifestyle".
Male, 61 years, score 23	"I have had regular blood sugar tests since 1995. The test results have always been negative".
***Male, 65 years, score 23**	"I'm surprised at my HR score. I'm very active and do lots of house renovations and heavy work".
Female, 65 years, score 23	Wrote on form – "score 23 but 8 for age" – "Some members of my family have diabetes".

5.10.3 Comments from HR participants who had not attended their GP

Within the HR group who completed the follow-up survey there were 23 HR participants (6 females: 17 males) who indicated that they would not make a specific appointment with their GP for a blood test based on their *AUSDRISK* HR score because they had regular/semi-regular GP appointments and would mention their AUSDRISK score at their next appointment.

Comments from 10 of these participants (3 female: 7 males) indicated they were already attending their GP either on a scheduled basis for monitoring of risk factors (high blood glucose, overweight) (Table 5.11) or were regularly seeing their GP for other health conditions (3 female: 10 male) (Table 5.12). Two male HR participants (scores HR1 and HR2)* chose not to attend their GP immediately as they considered they had already successfully implemented lifestyle changes (Table 5.11).

Table 5.11 HR participants who regularly attend GP for blood tests for T2DM risk will delay GP attendance to verify glycaemic status post* AUSDRISK *completion

HR participant/score Regular GP attendance for blood tests for T2DM risk	Comment on delay to attend GP to verify glycaemic status
Male, 65 years, HR1	"I have regular appointments with my GP to manage my high blood pressure. I'll mention the *AUSDRISK* result when I see him next. Thank you for reminding me"
Male, 60 years, HR1	"I have annual blood tests and they're due in 3 months, so I'll wait until then."
Female, 60 years, HR1	"I've had tests for diabetes previously and they've always been OK. I have a few other problems. Recently I've put on weight so I'm trying to do regular walking"
Male, 66 years, HR1	"My GP has already given me blood tests for diabetes. I've never heard about the *AUSDRISK* but I'll mention it to the GP".
Male, 61 years, HR2	"I see my GP regularly for blood pressure check. I remember filling in the "brochure", so I'll speak to GP about it."
Female, 65 years, HR2	"I have regular blood tests because both my parents have type 2 diabetes"
Female, 56 years, HR2	"My GP said my vitamin D levels were low, so he's put me on vitamin D capsules. When my vitamin D levels get back to normal, he'll re-test my blood sugar. My husband has type 2 diabetes, so I know the importance of a healthy diet and regular exercise".
Male, 66 years, HR2	"I'm not going to see my GP straight away because I have annual blood tests in 3 months' time."
***Male, 71 years, HR2**	"I have a blood test every 6 months. I had a heart attack 2 years ago. Since then I've lost 20kg by eating better and exercising."
Male, 61 years, HR3	"I have had regular blood sugar tests since 1995. The test results have always been negative."

Within the group of HR participants who had not attended their GP for a biomedical assessment prior to the follow-up survey but intended to do so, there were 10 HR participants who provided comment to explain the delay – four HR participants had forgotten to make an appointment and were pleased to receive a reminder, and the other six had regular GP appointments and planned to discuss their *AUSDRISK* result with their GP at the next scheduled appointment (Table 5.12). However, within this latter group of six persons,

two had seen their GP in the interim 5-6 week period but had forgotten/omitted to mention the *AUSDRISK* result to their GP.

Table 5.12 HR participants who regularly attend GP for other health conditions will delay/not attend GP to verify glycaemic status post* AUSDRISK *completion

HR participant/score Regular GP attendance for other health problems	Comment on delay to attend GP to verify glycaemic status
Female, 72 years, HR1	"I see my GP every week for injections for rheumatoid arthritis. I'd forgotten I completed the *AUSDRISK*. I'm seeing my GP next week, so I'll ask about testing for diabetes".
Male, 77 years, HR1	"I see my GP regularly because I have back problems. I didn't think about the *AUSDRISK* score, but I'll mention it at my next visit".
Female, 66 years, HR1	"I've just come out of hospital. I have blood tests every 3 weeks. I have asthma, epilepsy, atrial fibrillation. I'm trying to give up smoking, but I've been smoking for 46 years. My GP says diabetes is the least of my worries."
Male, 76 years, HR1	"I'm not going to see my GP about the *AUSDRISK* result. I have regular blood tests because I have cirrhosis of the liver."
Male, 65 score, HR1	"I see my GP regularly, so I don't plan to follow this up immediately."
***Male, 64 years, HR1**	"No, I'm not going to see my GP. I had major surgery due to a helicopter crash. I feel much better since the operation. I'm physically fit and eat really well."
Female, 61 years, HR2	" I haven't seen the GP yet. I've been busy with all the Xmas preparations. But I will go to the GP for a test".
Male, 67 years, HR2	"I see my GP regularly about other health issues, but I haven't seen him about the *AUSDRISK* result."
Male, 60 years, HR2	"I had blood tests before I had an operation 4 months ago and everything was OK then. So, I won't go to see my GP."
Male, 72 years, HR2	"I have a regular appointment with the GP every 3 months "
Male, 65 years, HR2	"I have a regular appointment with the GP every 3 months."
Male, 70 years, HR3	"Regular GP appt. Wife says he has every other ailment. Doesn't know whether checked for T2DM. Will ask at next GP appt"
Male, 60 years, HR3	"I didn't realise I had to see a GP for a blood test, but I'll mention it the next time I go to the doctor."

5.11 HR participants' knowledge of risk factors for T2DM

The 49 HR participants who provided comments were aware of the modifiable risk factors for T2DM such as overweight and obesity, poor diet, such as "*eating too much sugar, and not getting enough exercise" (as per quote)* a variation on a healthy lifestyle message as promoted by many government and non-government health organisations. Two HR participants commented they were restricted in the amount of exercise they could do because of *rheumatoid arthritis* and had not been advised of any medication that might assist them. Those with a family history of diabetes acknowledged they probably had a risk for developing diabetes, but that belief appeared to be based on personal experience, as per quote from one HR participants *"although not everyone in my family has had diabetes"*, rather than knowledge of the genetic-environmental complexity underscoring T2DM. Another HR participant who had experienced a family member with diabetes commented, as per quote "*I hope I don't get it as it was terrible"* and then proceeded to provide details of amputation, blindness and kidney failure.

When asked by the researcher, no HR participant reported knowing that ageing was a major risk factor for T2DM.

Of those HR participants who provided additional comments, none could understand the *AUSDRISK* rating score for older age groups, which many expressed as "*seeming unfair"* because "*you can't change your age"*. Two HR males were particularly dismissive, as evidenced by the following quote from a male aged 81 years – "*So just because I'm a man, I only need 1 more point and I'll be at high risk and there's nothing I can do about it"* (as per quote). The basis for his comment was the score for his age over 65 years (8 points) plus male gender (3 points) and one more point (e.g. not eating fruit and vegetables every day) would bring the total to 12 points (HR1). Another male HR participant questioned the validity of the *AUSDRISK* scoring for age and gender and refused to engage any further in the screening process, "*So, according to AUSDRISK all old guys are going to get diabetes. That's rubbish."* (as per quote).

5.12 Summary of findings by objectives

The first objective was recording the number and details of HR participants who did/did not complete the follow-up survey, in this way this study was able to demonstrate that the drop in participation at each step of the screening process, which had been noted in the earlier stages, continued during the follow-up survey and GP attendance. There were 136 participants who scored HR; 108/136 consented to complete a follow-up survey; and 92/108 completed the follow-up survey.

Analysis of participation numbers and rates in the follow-up survey showed the numbers and rate of those recruited indirectly through the mail out was significantly greater than those directly recruited in health service settings. However, there were no significant differences in age, gender, HR score level and family history between those who completed or did not complete a follow-up survey.

The second objective was to record and compare the number and details of HR participants who completed the full screening sequence and compare these findings with the details of those HR participants who did not complete the full screening. There were no significant differences between those who attended or did not attend a GP for biomedical assessment by HR score levels (P=0.44), age (P=0.54) gender (P=0.14) or recruitment type (P=0.52: P=0.33). There was no significant difference in GP attendance by males who scored at different HR levels. Analysis of GP attendance by gender showed that HR score levels did not influence males' behaviour to attend their GP. Analysis of GP attendance by females in different HR levels showed there was a significant difference between females in the HR3 level who were significantly more likely to attend their GP compared to females in the HR1 level. There was no significant difference in GP attendance between females in HR2 and HR1 levels. Overall the difference in pattern for GP attendance between HR males and HR females was statistically significant, with females more likely to attend their GP for biomedical assessment than males.

The third objective was to record the results of the blood test (as reported by the HR participants) and determine the predictive value of the *AUSDRISK* HR score level in relation to the older age HR participants' glycaemic results. GPs ordered blood tests for 49/50 older-age HR participants. The blood test results of the 49 HR participants showed that 42/49 (85.7%) were normoglycaemic; and 14.3% (7/49) had EBG. No older-age HR participant was assessed as having T2DM. Therefore, the *AUSDRISK* HR scores in this study of older-age participants had a positive predictive value of zero for T2DM. Elevated blood glucose (EBG) levels were found across all HR levels (HR1 = 10.0% (2/20), HR2 = 17.6% (3/18), and HR3 16.7% (2/12). There was no association between the older-age participants' HR score levels on the *AUSDRISK* and the diagnosis of EBG. Those who were biomedically assessed as having EBG had a risk score that was on average only 0.95 units higher (p=0.50) than those at HR who were biomedically assessed as normoglycaemic.

In summary, from a total of 136 HR older-age participants, 36.8% (49/136) completed the full screening process with no HR participant found to have T2DM,14.3% (7 HR participants) had EBG/preDM, and 85.7% (42/49) had a normal blood glucose level. Furthermore, there was no significant difference in HR score levels for those at HR who were biomedically assessed as having EBG/preDM, and those at HR who were biomedically assessed as having blood glucose levels in the normal range.

The fourth objective was to record the GPs' actions (as reported by the HR participants) on being advised of the participants' HR *AUSDRISK* score, and note the GP directions to the HR participants based on their blood test results. Those with EBG were advised by their GPs that in future they would have regular blood glucose monitoring and needed to make lifestyle changes to reduce their risk for T2DM. No HR participant with EBG was prescribed medications to reduce blood glucose. Of the HR participants found to be normoglycaemic, 70% were advised by their GP to make lifestyle changes. None of the HR participants assessed as normoglycaemic recalled being advised they should continue to have regular

blood glucose tests. This is not to say that some/all were not informed of this by their GP but rather they had no recollection of this.

The fifth objective was to record the free text information provided by HR participants on their knowledge, beliefs and attitudes regarding the *AUSDRISK*, T2DM and risk for T2DM, including their response to their blood test results. A main finding related to this objective was that none of the HR participants was aware that older age was a major risk factor for T2DM. Secondly, approximately 90% had never heard of the *AUSDRISK.* Review of comments from HR participants who completed the follow-up survey and attended or did not attend for a biomedical assessment showed that close to 100% were already attending their GP on a regular basis, ranging from annual attendance (for a general health check) to fortnightly depending on need. Of those who provided comments 50.0% specified they had other illnesses for which they were attending their GP, and 50.0% had regular comprehensive blood tests which included assessment of blood glucose. The comments provided by 49/92 HR participants indicated they had an established relationship with their GP and were guided by the GPs recommendations and directions. The close relationship between older adults and their GPs with regard to their health and in particular T2DM screening, prevention and management would suggest that participation in screening for T2DM and its precursor preDM would be best achieved through this established system.

In addition, this study found that older-age participants were not familiar/very unaware of the AUSDRISK tool. This made it difficult to estimate the impact of this lack of knowledge of the *AUSDRISK* on the initial participation rate, and the follow through to complete the T2DM screening process. Earlier research (Lavielle et al 2014; Davey et al 2015) had shown that a HR score had the risk averse effect for those scoring HR by their not following through to a biomedical assessment.

Using the *AUSDRISK* as the first step in T2DM screening in an older cohort was not an efficient process, in that many older individuals chose not to participate initially, and of those who scored HR, many chose to delay obtaining a blood test to verify their glycaemic status

until attending a pre-booked GP appointment sometime in the future. As the *AUSDRISK* was unfamiliar to most older participants, and preDM/T2DM have very few symptoms in the early stages, they may well forget/or not consider necessary to mention their HR score to their GP.

Overall, this study showed that older individuals' knowledge of risks for T2DM is markedly lacking. As they are in a high risk group for preDM/T2DM due to their age, they would benefit from age-specific health information and health promotion aimed at having their risk for T2DM regularly assessed.

Chapter 6. Discussion

6.1 Introduction

The research described in this thesis was undertaken, in 2014–15. At that time there had been no systematic implementation of the *AUSDRISK* as the first step in a T2DM screening program for identifying older individuals with or at HR for T2DM. Both the Australian National Health & Medical Research Council (NHMRC) Evidence-based Guideline for Case Detection and Diagnosis of Type 2 Diabetes (Colagiuri et al., 2009c) and the Royal Australian College of General Practitioners (RACGP) Guidelines for Preventive Activity in General Practice (Royal Australian College of General Practitioners, 2014) had recommended completing the *AUSDRISK* every 3 years as the first step in screening adults ≥ 45 years considered to be at risk (by their GP) for undiagnosed T2DM prior to biomedical assessment. However, a study by Wong et al., (Wong et al., 2011) found it was rarely used by GPs in Australia. As at 2019 the guideline recommendations remain the same (Royal Australian College of General Practitioners, 2018) and the *AUSDRISK* is still rarely used by GPs. The *AUSDRISK* is available in print and on-line but not regularly publicised. The *AUSDRISK* is promoted for self- assessment annually in health promotion events such as *Diabetes Week* or *World Diabetes Day* by the non-government organisation *Diabetes Australia* and its state-based organisations. The *AUSDRISK* score has been used as a basis for identifying HR participants for short term state-based T2DM prevention programs for individuals in the 45-74 year age range; mean 57 (9.6) years (Aguiar et al., 2015, Dunbar et al., 2015, Johnson et al., 2015, Malo et al., 2015) but no similar programs had, or subsequently have been conducted in Tasmania.

Tasmania has the oldest population of any state/territory in Australia. As with many chronic health conditions the risk for, and occurrence of, T2DM increases with age. In 2014-15, *Diabetes Tasmania* reported that 26.9% of individuals newly diagnosed with T2DM were aged 70 years and over. The primary aim of this research was to determine the effectiveness, acceptability and feasibility, of implementing the *AUSDRISK*, in community-

based non-medical healthcare and non-healthcare settings in Tasmania to screen older individuals aged 50 years and over for T2DM and identify those with undiagnosed T2DM or at HR for developing T2DM at an earlier age than was currently occurring.

A real-world multi-methods strategy (Fetters et al., 2013) was chosen to capture the range of influences, both positive and negative, impacting on this *AUSDRISK* screening strategy particularly with reference to the older age cohort. In order to evaluate this complex primary aim, a series of linked objectives were implemented to reflect the sequential steps taken in this T2DM screening initiative. These objectives were, in sequence, to determine the uptake/initial interest shown by this age-specific cohort in assessing their risk for T2DM by completing an *AUSDRISK*. Next, to determine if those older individuals assessed at HR, continued in the screening process to attend their GP for a biomedical assessment, and, for those HR older individuals who did attend their GP, to assess the positive predictive value of the *AUSDRISK* HR scores, by comparing the participants' HR score levels with their blood test levels (normal glucose level; elevated blood glucose; T2DM). Finally, to identify systemic (medical and non-medical) and personal factors which act as facilitators or barriers to implementing a community based T2DM screening process for older adults.

However, as the major finding in this research was that *AUSDRISK* HR scores had zero positive predictive value for identifying T2DM in an older age cohort, this finding will lead the Discussion chapter.

6.2 Overall findings

6.2.1 Effectiveness of *AUSDRISK*

The major finding in this T2DM screening research project, showed that no older age individual (mean age 65.5 years) assessed as HR on the *AUSDRISK*, was identified as having T2DM on blood glucose testing, 14.3% HR were identified as having elevated blood glucose (EBG) and 85.7% HR had a normal blood glucose level. There was no association between the actual HR score level (HR1; HR2; HR3) on the *AUSDRISK,* and the diagnosis of

EBG. Those who were biomedically assessed as having EBG had a risk score that was on average only 0.95 units higher (P = 0.50) than those assessed as HR who subsequently were identified as being normoglycaemic, on blood glucose testing. Older participants with Elevated Blood Glucose (EBG) levels were found at all HR levels from HR1 to HR3 and not just HR2 and HR3 as predicted by some Australian diabetes prevention studies using *AUSDRISK* HR cut-off points as the entry level for diabetes prevention programs (Dunbar, 2017, Dunbar et al., 2015, Lee et al., 2018, Malo et al., 2015). At the time this research was conducted, this lack of association between HR score levels and blood glucose test results, was not expected.

The *AUSDRISK* screening project was conducted according to the NHMRC Guidelines for the Case Detection and Identification of Type 2 Diabetes, with completion of an *AUSDRISK* as the first step in the screening process to identify those at HR prior to implementing a blood glucose test (Colagiuri et al., 2009c). To reiterate, the purpose of completing an *AUSDRISK,* as the first step in T2DM screening, is to first identify those at HR, prior to a GP determining to initiate blood glucose testing. This is considered an efficiency measure to overcome the expense of implementing a FPG or HbA1c blood test for all individuals over the age of 45 years, who show evidence of being at HR for T2DM (Lee et al., 2018).

In this research 44.2% older adults (mean age 65.5 years), were identified as being at HR, that is, scoring 12 points or more. This percentage of older individuals at HR was two-fold higher than the predicted percentage at HR (21.1%) when the *AUSDRISK* HR2≥15 minimum score alone was used to classify the HR category in a modelled study by Lee et al (Lee et al., 2018) based on participants aged 45–74 years with a mean age for men of 58.2 (9.5) years and for women 56.9 (9.5) years.

Despite the higher percentage of individuals at HR (by *AUSDRISK*) in this study of older individuals, the resultant percentage of HR individuals shown to have EBG levels on biomedical assessment was consistent with results from other Australian T2DM screen and

prevention programs which, after eliminating individuals with diagnosed diabetes (all types), used the *AUSDRISK* to identify HR individuals (age range 45–74 years) for admission to T2DM prevention programs, (Dunbar et al., 2015, Malo et al., 2015). Those studies were the Melbourne (Victoria) Diabetes Prevention Study (Dunbar et al., 2012, Dunbar et al., 2015) and the Greater Green Triangle study in Victoria (Dunbar et al., 2014) where 84.8% of HR participants were found to be normoglycaemic and 15.2% had EBG on biomedical assessment.

The decision to make a HR2 score 15/16-19 on the *AUSDRISK* (prediction of 1 person in 7 HR developing T2DM within 5 years) as the minimum entry level to T2DM prevention programs was on a cost-efficient basis. The previous researchers did acknowledge that some individuals scoring HR1 may be missed (HR 1 = 12–15; with a prediction of 1 in 14 developing T2DM within 5 years). However, my study found there was no association between the older-age participants' HR score levels on the *AUSDRISK* and the diagnosis of EBG. Therefore, according to my findings of EBG/preDM at all levels of HR, to determine that those who scored HR2 and HR3 were likely to be at greater risk than an individual scoring HR1, may need to be reconsidered in relation to older adults.

As stated in the introduction to Chapter 5, as the *AUSDRISK* had been found not to be effective in an older age cohort, there may be little point to continuing with the feasibility and acceptability of *AUSDRISK* in T2DM screening in older individuals. However, the findings in relation to these two essential components of screening are equally applicable to other T2DM screening practices. The benefit of taking a multi-method approach to this screening study has been the opportunity to evaluate the quantitative results in relation to the qualitative/subjective comments provided by the older HR individuals who completed the follow-up survey. Their comments provided valuable insight and clarification for the older age participants' responses, attitudes and observed behaviour towards T2DM screening.

Therefore, in order to examine the inter-related aspects of this research, the ongoing discussion will be presented in sections relating to each of the study's objectives. Finally, a

discussion on the implications of this study's findings for future policy and practice for T2DM screening, with or without utilizing *AUSDRISK*, for those in the *young-old* cohort, will complete the chapter.

6.3 Feasibility of distribution of AUSDRISK

6.3.1 Distribution

This study found that the actual distribution of the *AUSDRISK* plus information/instruction/ consent form was feasible via direct distribution by local healthcare services and indirectly via a non-healthcare Seniors Card mailout. The direct healthcare service face-to-face presentation was more effective in initially recruiting older age individuals to complete an *AUSDRISK* than the Indirect method. In both the Direct and Indirect recruitment participation was voluntary. The high level of initial recruitment via direct *AUSDRISK* presentation in health services appeared to be due to the health service setting, with the opportunity for health service staff (if asked) to verify the purpose of the *AUSDRISK* and help with waist measurement (if requested). This direct interaction with a health service staff member was in addition to the printed material provided which explained the purpose and rationale for completing an *AUSDRISK*. The recipients of the *AUSDRISK* via mailout had the same printed information but not the verbal interaction face-to face with health service staff. In the planning stage this potential difference was acknowledged, as the study wished to determine if there were any differences in uptake of the *AUSDRISK* by the way it was presented to the potential participant. One reason for choosing the Seniors Card (SC) mailout service, apart from convenience and cost effectiveness, was that the SC mailout was an acknowledged and reputable service specifically for older age individuals and had been used previously for health promotion material such as Falls Prevention information.

The initial participation numbers of individuals recruited through mailout to complete an *AUSDRISK* clearly indicated that, in future age-specific information about T2DM, age related risks for T2DM, explanation of "risk" as opposed to a diagnosis, and the benefit of knowing

your T2DM risk, would be needed to promote/encourage more participation of older individuals indirectly recruited. Recent articles by Harte et al, and Usher-Smith et al (Harte et al., 2017, Usher-Smith et al., 2017) on reasons why people do not attend *the NHS Health Check programme* and patient experiences of *the NHS Health Check programme* found there was insufficient communication targeted to the expected recipients, on the potential benefits for prevention and early detection of CVD/T2DM, along with the knowledge of purpose of the risk assessment tool/protocol, in order for screening to be effective.

6.3.2 Staffing issues for direct *AUSDRISK* distribution

On completion of the research study, health care professionals in the Integrated Care Centre and in the two optometry practices who participated in implementing the *AUSDRISK*, were interviewed. In this post-research interview, the healthcare professionals expressed concern about the time taken for the *AUSDRISK* introduction and completion which reduced the time available for addressing the patient's clinical needs for which they had attended the service, thus creating stress and inconvenience for both clinicians and patients. The time to complete an *AUSDRISK* and other risk assessment tools (Aujla et al., 2013, Stone et al., 2014) has been documented as a potential limiting factor in national and international T2DM prevention initiatives (Dunbar et al., 2015, Krass et al., 2007, Malo et al., 2015).

During the planning phase of this study, time to introduce and complete *AUSDRISK* was discussed with the health professionals who appreciated the benefit of implementing the *AUSDRISK* and considered that there would be sufficient time and staff to introduce and have the *AUSDRISK* completed. In reality, this proved not to be the case. The administrative (in-take) staff in the Integrated Care Centre were found to be best suited to present the *AUSDRISK* within their usual new patient admission duties. The duty roles of the administrative staff in the two optometry practices did not allow their participation in presenting the *AUSDRISK* as this initiative came under the description of providing health services and, as such, was not allowed. This had not been anticipated as a difficulty during initial planning. Older-age participants took longer time to complete the *AUSDRISK* than

optometrists expected due to lack of familiarity with the *AUSDRISK*, which potentially impacted on the provision of optometry services.

In terms of overall numbers of individuals approached to participate, there was only a small impact/reach via those attending the particular health services whether that be the Integrated Care Centre or the optometry practices. The 'reach' could be extended and standardised as part of a new patient assessment for all services in an Integrated Care Centre, but this would require a considerable systems management change and still remain vulnerable to local implementation issues. Most older participants recruited via optometry practices did not perceive optometry services as having a role in T2DM screening and identification, although optometrists are often the first health professional to note changes in the eye-health status indicative of prediabetes (personal communication with participating optometrist). Optometry services were considered by most clients as health improvement services for individuals in good general health. As an aside, people with T2DM are allocated with free *Medicare*-funded optometry services to ensure good eye health. It would appear that the general public is not aware of this service. The optometry settings had the lowest participatory rate of all the direct settings and this lack of knowledge regarding the role of optometry in T2DM prevention and management may account for the lack of interest in participation.

The three Seniors Card mail-outs to 1500 (3 x 500) older adults was superior (to the direct healthcare implementation) in its equitable 'reach' statewide. Use of an established and regular mail-out system with specific access to the older age community had the potential to make the *AUSDRISK* available to a wide range of older adults, including those so-called 'hard-to-reach' clients who may not be regularly accessing medical/health services. Unfortunately, this proved not to be the case, as will be discussed later in this chapter. The mail-out also had the advantage of being independent of demands on the staff and staff time, in health services. Furthermore, the mail-out had the potential to be linked to initial recruitment with other established Australian national health-screening mail-outs to older age

individuals, such as those for colorectal cancer(Cenin et al., 2014) and breast cancer screening,(Hersch et al., 2011).

In Australia, the breast cancer screening and colorectal cancer screening programs use mail out notification and decision aids (Hersch et al., 2014, Hersch et al., 2011) to great effect, both to facilitate initial participation, and also as a reminder to those individuals who had not responded within a pre-set time. This approach is used in UK, US and European cancer screening and T2DM screening programs (Alberti et al., 2015, Essink-Bot et al., 2016, Wardle et al., 2016) (Khunti et al., 2015). However, the recipients of the *AUSDRISK* via mail out in this research did not have the opportunity to be reminded or encouraged to participate. Unfortunately, in order for this study to gain permission from the Tasmanian State Government to utilise three Seniors Card mail-outs for statewide distribution of *AUSDRISK*, the researcher was not permitted to know the names/addresses of recipients. The role of the Seniors Card bureau was to arrange the three mailouts and provide information on the geographic distribution of *AUSDRISK* across the state. Follow-up of recipients of the *AUSDRISK* was not part of the Seniors Bureau agreement. Under that agreement a reminder system could not be used to facilitate an increase in initial participation. Recruitment of participants in future studies would benefit from ensuring a reminder facility is allowed and included. In this research, subsequent contact could only be made with those HR participants who provided a separate signed agreement and contact details to participate in the follow-up survey, which followed the initial *AUSDRISK* completion.

6.4 AUSDRISK uptake/interest

This study found that although the *AUSDRISK* was effectively distributed, the interest and initial response rate of this older age group to being invited to assess their risk for T2DM was limited. The overall uptake (Direct and Indirect) of the *AUSDRISK* in this study was 17.6 per cent. Although this may appear to be low, it was greater than the 8.6% response rate of the first *MY-WAIST UK T2DM* mailout study (Aujla et al., 2013) and comparable to the uptake of first mailout recruitment for the *NHS Health Check program* in 2009 (Gidlow et al., 2015,

Robson et al., 2016). The uptake was also comparable to the initial 18% uptake of the large baseline survey for *The 45 and up Study* in Australia in 2015 (Bauman et al., 2016). A low response rate to new initiatives when first presented has been noted in other international T2DM and CVD screening programs (Aujla et al., 2013, Eborall et al., 2012, Groenenberg et al., 2016, Groenenberg et al., 2015) and T2DM screening/prevention studies in Australia (Dunbar et al., 2015), and therefore it was not a surprising finding in this study.

The impact of the difference in recruitment rates between the Direct and Indirect groups was somewhat reduced at a later stage in the screening process, when information became available from the HR follow-up survey and GP attendance. The results from those sources revealed that 37.0% HR responders recruited via the Seniors' Card mailout had completed the follow-up survey and GP attendance, whereas only 15.9% of the HR participants invited via a health service completed the full follow-up to completion of survey and decision to attend/not attend for biomedical assessment. This latter finding would suggest that once the participants, recruited directly via face-to-face by healthcare staff, were removed from the personal connection, they reverted to more usual behaviour. The concept of social desirability bias, that is *"to do the right thing",* may have been in evidence in the initial completion of an *AUSDRISK* when it was presented directly. If the participants' health literacy was poor, the default position would likely be to cease any further involvement with follow-up. This pattern of behaviour has also been noted in *the NHS Health Check programme* (Usher-Smith et al., 2017). Whereas those indirectly recruited via mailout had voluntarily made their choice to participate in the screening program, and they showed a greater preparedness to follow-through to GP attendance than those directly recruited. Comments made during the follow-up survey by HR participants recruited through the Seniors Card, also indicated that they were familiar with the GP/primary healthcare system. This familiar relationship was also likely to have facilitated their ongoing participation.

The level of health literacy of older Tasmanians was difficult to determine. In 2014 the *Facing the Future Report* compiled by the Tasmanian Council on the Ageing 2014 (Council on the Ageing Tasmania, 2014) reported that many older Tasmanians had poor health literacy. The Australian Commission on Safety and Quality released the *National Statement on Health Literacy- taking action to improve safety and quality* (Australian Commission on Safety and Quality in Health Care, 2014) in recognition of the need to improve health literacy. However the Tasmanian Population Health survey 2016 (Tasmanian Department of Health and Human Services, 2016) reported that close to 90 per cent of older individuals indicated that they had no difficulties communicating with their doctor and understood medical information and instructions. It would appear unlikely that there had been a dramatic improvement in health literacy over a two-year period. Rather, that older individuals could follow instructions provided by their GP, as opposed to comprehending the nature of a chronic health condition.

Overall the findings suggest that there was not sufficient information relevant to older age and T2DM risk in the *AUSDRISK,* and on the instruction/consent sheet to facilitate older age participation in self-assessment of T2DM risk. This lack of knowledge appears likely to have been reflected in the limited initial uptake, and a reduction in numbers of HR individuals following-up at subsequent steps in the screening-to-biomedical assessment process. That being the case, added age-related information regarding the benefit of 'knowing your risk' may prove to be an essential factor to encourage participation via both health service and mail-out recruitment, as has been found in the US, UK (Usher-Smith et al., 2017) and in European countries, and in Australia, in bowel cancer (Duncan et al., 2013, Flitcroft et al., 2010) and breast cancer screening programs (Hersch et al., 2014, Hersch et al., 2011). In addition, these cancer screening initiatives have an established and well-promoted regular screening system, which in addition to the actual screening process, recognises the need for promoting awareness and facilitating engagement in screening for early identification (Rockliffe et al., 2018). The follow-up research of the large Australian *45 and up Study* was

designed to determine effective strategies for maximizing response rates. It found that mailing advance notice postcards to prospective participants followed by reminder notices (for those who had not responded) increased the response rate from 18% to 61.6% (Bauman et al., 2016).

As noted in the previous chapter, at the time of initial recruitment for the AUSDRISK study, there was no way of accurately determining older individuals' knowledge of T2DM, including knowledge of the purpose and value of screening for T2DM, the use of *AUSDRISK*, and the modifiable and non-modifiable risk factors for T2DM. However, the purpose of implementing a real-world approach was to present the intervention in a manner recommended in the National Evidence Based Guideline for Case Detection and Diagnosis of Type 2 Diabetes (Colagiuri et al., 2009c), which in this case was to use *AUSDRISK* as the first step in screening for T2DM in a targeted intervention for a HR group. By implementing the *AUSDRISK* in the prescribed manner, the issues that would impact positively or negatively on participation in a T2DM screening study using *AUSDRISK* for older individuals would become apparent. The comments of those HR participants who subsequently completed the follow-up survey showed evidence of a low level of diabetes-specific health literacy (i.e. functional literacy) in older individuals in both the Direct and the Indirect recruited groups in this study.

When all the factors involved in the distribution and uptake of *AUSDRISK* were considered, it would appear that a mailout such as the Seniors' Card mail-out with greater reach for a targeted older-age population would be the preferred approach. The potential for increased uptake if reminder notices, and targeted information on the benefit of T2DM screening for older individuals were implemented, could be explored, to determine if increased initial and follow-up participation occurred (Bauman et al., 2016). However, in view of the lack of effectiveness of *AUSDRISK*, perhaps an initial postcard alerting older-age individuals to the age-related risk of T2DM, followed by a notice to attend for a direct biomedical assessment such as an HbA1c test, might be considered.

Despite the limitations associated with recruitment, HR individuals were identified in all recruitment settings. The pattern of *AUSDRISK* scores was consistent through all HR levels with the greatest number of HR participants scoring in the lowest HR1 level, and the least number scoring in the highest HR3 level. This result was present across all recruitment settings which would indicate comparable levels of T2DM risk across individuals recruited via different settings. However, there was a noticeable difference in gender balance between those initially recruited via Direct and Indirect settings. In the initial Indirect recruited cohort, there were equal numbers of males and females recruited (101 males and 101 females). In the initial Direct recruited cohort, there were twice as many females as males (32 males and 68 females). Without knowing the gender distribution of all individuals who received an invitation to take part in this research, it is not possible to determine the significance of this finding. The reason for the greater female to male participation in the Direct recruitment setting appears likely to be that females are known to access health services more frequently and in greater numbers than males, as noted in the ADDITION-Leicester study (Bodicoat et al., 2017, Davey et al., 2015, Dunkley et al., 2014). However, in the total HR cohort in this research, there were more males than females, and this pattern was also reflected at each of the HR levels. Again, this finding seems more likely to have been related to the *AUSDRISK* scoring which has an additional 3 points for being male gender to reflect the prevalence of T2DM being significantly greater for males than females.

6.5 Impact of the hard copy AUSDRISK

The *AUSDRISK* is now available in two formats (printed and e-copy), although at the time of this research it was only available in printed copy. An on-line electronic copy may be accessed via the *Diabetes Australia* website (Diabetes Australia, 2015) (and its state-based organisations) and government health sites (Australian Government Department of Health and Ageing, 2008). For this research, the hard copy of *AUSDRISK* was used, which has the points score placed against each risk factor. Whereas in the electronic copy, scores are not placed against risk factors, and the overall test result/score is presented on completion of all

the risk factor questions. Comments provided by HR participants in this research indicated that the availability of each risk factor score caused confusion, and for at least one potential participant caused him to dispute the validity of the *AUSDRISK* and refuse to engage any further in the screening process.

The scoring points for age group and gender (as printed on the *AUSDRISK*) that reportedly caused the most disquiet for participants were:

Table 6.1 AUSDRISK Scoring system for risk

Your age group	
Under 35 years	0 points
35–44 years	2 points
45–54 years	4 points
55–64 years	6 points
65 years or over	8 points
Your gender	
Female	0 points
Male	3 points

Of those HR participants who provided additional comments, none could understand the *AUSDRISK* rating score for older age groups, which many expressed as "*seeming unfair*" because "*you can't change your age*". Some HR participants were dismissive particularly in regard to the scores apportioned for age and gender. For others, the confusion was associated with the age ranges, which is the first item on the *AUSDRISK,* where some participants considered the age group printed on the *AUSDRISK* was there to reflect their biological age range, rather than the number allocated to each age-range indicating the predicted risk for T2DM associated with that age group, and one participant actually reduced the final score by subtracting the number apportioned for age. Had an electronic version of the *AUSDRISK* been utilised, the participants would not necessarily have been so aware of the individual risk scores, particularly those linked to the non-modifiable risks. Whilst this may

have reduced their concern during the completion of the *AUSDRISK*, it would not have highlighted the distribution of their risk whether that be due to modifiable or non-modifiable risk factors.

6.6 HR participants' follow-up actions

6.6.1 Follow-up Survey – actions of HR participants

As indicated in the preceding chapters, the *AUSDRISK* is a Risk Assessment Test (RAT) and does not provide a diagnosis of T2DM. Therefore, in order to complete the screening process, an individual assessed as HR on the *AUSDRISK* is advised, by information on the *AUSDRISK* form, to attend their GP for a Fasting Blood Glucose Test (biomedical assessment) as they may have type 2 diabetes.

By recording the number and details of HR participants who did/did not complete the follow-up survey, this study was able to show that the decrease in participation occurred at each step of the screening process, from the early stages of the screening process, through to the follow-up survey and GP attendance. This response pattern has been noted in international studies (Davey et al., 2015, Echouffo-Tcheugui et al., 2009, Hanoch et al., 2016).

There was no significant difference in risk score levels between those who attended or did not attend for a biomedical assessment. The proportion of HR individuals attending their GP for assessment of their glycaemic status increased as the level of risk increased from lowest HR1 level to the highest HR3 level, which would suggest that participants had "self-assessed" their risk and determined their need to see their GP according to the *AUSDRISK*'s total risk score prediction for developing T2DM within a 5-year period, that is: HR1 = one person in fourteen; HR2 = one person in seven; and HR3 = one person in three. This self-assessment has been noted in T2DM screening initiatives internationally (Hanoch et al., 2016).

Although there was an increase in overall attendance to non-attendance for biomedical assessment as the level of High Risk increased from HR1 to HR2 and HR3, this was not observed for both males and females. There was a significant interaction between HR participant's gender, risk level and GP attendance or non-attendance. The response pattern of HR males for attending/non-attending GPs for a biomedical assessment was not influenced by their level of HR. Whereas HR females showed the highest level of GP attendance when their level of HR was greatest (HR3) and lowest attendance associated with lowest risk (HR1). This gender difference in GP attendance is well known, with males being known to have lower health knowledge and attention to disease prevention than females (Davey et al., 2015). As males have a higher prevalence and incidence of T2DM, the male response pattern of not increasing engagement with perceived increased personal health risk (Davey et al., 2015), would be an additional challenge to address for any T2DM screening program. However, for this study it must be acknowledged that the numbers of HR participants-by-gender are small and may lack sufficient power to support a conclusion on this occasion.

The major finding of the reduction in numbers of participants at each "next stage" of the screening process is not an unusual finding in the Australian Health system, in that in a multi-stage screening process which involves different sectors in the health system, there is a loss of participants between stages for a variety of reasons including personal cost, time, and personal estimate of need to continue with the assessment process or not. These same factors had been noted in international screening initiatives (Harte et al., 2017, Usher-Smith et al., 2017). In Australia individuals are not registered with particular GPs or GP practice, so for many individuals/families there is no appreciation of the benefit of a long-term record to systematically follow a sequence of prevention and management initiatives to address recognised risks for developing chronic conditions such as T2DM.

The Australian Government is attempting to overcome the lack of integration of personal health data by the introduction of the new *MyHealth* record which is expected to provide a

long-term electronic record of all health-related interventions at an individual level across primary and secondary health care. Unfortunately, there has been an initial rejection for immediate implementation (December 2018). Whilst opt-out reasons for the *MyHealth* record are complex, the people who opt out are at least saying that they do not see the benefit of an enduring health record as outweighing their other concerns (be they privacy or whatever).

Nevertheless, reminder notices implemented within an established system to encourage greater initial and follow-up participation in pre-DM/T2DM screening, have been effective in increasing numbers of participants in T2DM screening in UK and Europe (Groenenberg et al., 2016, Groenenberg et al., 2015, Sussman et al., 2015, Van Den Donk et al., 2011).

6.6.2 Actions of GPs in response to HR participants' attendance

For those HR participants who were determined to learn their glycaemic status by taking their completed *AUSDRISK* to their GP, most general practitioners responded as recommended (Colagiuri et al., 2009c, Royal Australian College of General Practitioners, 2014) by ordering blood glucose tests and providing lifestyle modification advice. The HR clients biomedically assessed as currently normoglycaemic reported that GPs had discussed potential lifestyle modification in general terms, rather than in a specific and personalised manner suited to the needs of each HR participant. Ongoing regular monitoring was only recommended to those assessed as having elevated blood glucose (EBG). The GP response (reported by HR participants) of "keeping an eye on the situation" was given to those assessed as having elevated blood glucose. This appeared to be done to alleviate the participants' concerns. However, whilst acknowledging the known variability of blood glucose levels, the HR participants with EBG reported that their GP did not suggest implementing a confirmatory blood glucose test immediately, or in the near future.

The HR individuals who were found to be normoglycaemic on biomedical assessment reported that the GP had not stated that they would be tested again in 1-3 years (as recommended by NHMRC Guidelines). This is not to say that the GP would not implement

regular testing, but rather that the HR individuals were given no expectation of this. GPs appeared to be responding to their patients' current normoglycaemic status rather than their potential ongoing risk associated with increasing age, with or without additional lifestyle or other biomedical risks. This limited reinforcement appeared to inadvertently reduce the HR individuals' perception of their ongoing T2DM risk due to ageing.

The impact of similar patient/doctor interactions and resultant perceived risk reduction on the part of the patient has been noted in UK and US screening studies (Godino et al., 2014b, Mainous 3rd et al., 2016b). In addition, this would appear to be a missed opportunity on the part of the GP to educate HR individuals about the progressive nature of T2DM and what "High Risk" means; the rationale for regular monitoring of blood glucose status, and the benefit of effective lifestyle behaviour change as a protective measure to reduce or stabilise their risk for preDM/T2DM. The issue of missed opportunity in this educative component has also been noted in international T2DM screening in primary health care (Mainous 3rd et al., 2016b).

A survey by Tseng E et al (Tseng et al., 2017) reported that many US primary care physicians lacked knowledge of risk factors, diagnostic criteria and management and prevention of prediabetes. However, in the Australian primary healthcare context, the limited educative component may be due in part to the short time-limited Medicare funding for GP consultations. Overall, however, the reported GP responses suggested a hierarchical management on the part of the GPs, rather than a collaborative approach including the patient/participant. For most older age HR participants, relying on the GP for guidance and direction was acceptable as usual practice (Mainous 3rd et al., 2016a, Mainous 3rd et al., 2016b).

In collating the comments received from HR participants, irrespective of whether they had scored EBG; scored HR3; chose not to attend their GP, or planned to attend GP for biomedical assessment, it was clear that all participants had regular (weekly to yearly) contact with their GP for a variety of reasons. There may have been some hard-to-reach

individuals recruited, however if they were initially recruited, they did not complete the full assessment. This was disappointing as the Seniors Card mailout was used in an attempt to access older individuals who may not be attending, or being financially or geographically unable to attend, their GP on a regular basis. Perhaps this was somewhat ingenuous considering that most of the information that would encourage older age individuals to participate in T2DM screening would be received via GP contact. (Royal Australian College of General Practitioners and Diabetes Australia, 2016-18).

6.7 HR individuals' T2DM knowledge and response

When the resultant outcomes of the screening process were considered in the light of comments from those who scored High Risk, it showed that less than one third of those individuals assessed as HR (30.6%) actually completed all the follow-up actions and attended their GP for a biomedical assessment. The researcher specifically asked those participants who completed the follow-up survey by phone, whether they were aware that older age was a risk factor for T2DM. No participant was aware of this fact. Ninety per cent of the survey respondents stated that they had never heard of the *AUSDRISK*, despite its being available in print and on-line since 2010. This unfamiliarity with the questionnaire and its purpose, together with their lack of knowledge that increasing age was an independent risk factor for developing preDM/T2DM, appeared to have adversely influenced initial and follow-up participation (Rockliffe et al., 2018). Poor health literacy has been implicated as a barrier to initial participation and completion to biomedical assessment in other international T2DM screening studies (Aujla et al., 2013, Godino et al., 2014b, Kalyani et al., 2013, Lavielle et al., 2014).

Many survey respondents stated they found the scoring for older age participants to be unfair and "ageist" as it was a non-modifiable risk. This study did not have the capacity to determine the extent to which this attitude, associated with a lack of knowledge regarding modifiable and non-modifiable risk factors, may have contributed to older adults declining to participate in the *AUSDRISK* screening program, either initially, by not undertaking the

survey, or after completing the *AUSDRISK* and scoring HR, by not attending for biomedical assessment. The majority of those assessed as HR indicated some concern regarding their level of risk for T2DM. In addition, there were those who stated they were very active and fit, and therefore could not understand why they were assessed as HR. Research by Grzywacz et al (Grzywacz et al., 2014) noted that belief patterns varied by the extent to which popular beliefs on T2DM formed the basis of knowledge rather than biomedical information. Those who had a biomedical assessment, and were found to be normoglycaemic, reported being very relieved and considered themselves to be no longer at risk for T2DM, which suggests they considered the *AUSDRISK* results to be diagnostic rather than an estimate of ongoing risk for T2DM. This belief was consistent with recent findings internationally (Mainous 3rd et al., 2019). This HR participant attitude persisted despite the fact that their GPs had provided them with general lifestyle modification advice to reduce their T2DM risk. A similar response and lack of understanding of risk was reported by the ADDITION - Cambridge study (Paddison et al., 2009) which found that negative biomedical screening results (i.e. normoglycaemia) did not lead to either positive or negative lifestyle modification over a 7-year follow-up.

From a health promotion viewpoint, the participants' responses indicated limited health literacy in understanding the concept of risk and ongoing risk. However, their responses in regard to their unawareness of increasing age being a major risk factor for T2DM most likely reflected the emphasis that continues to be taken by health professionals and *Diabetes Australia* on promoting adverse lifestyle risk factors such as overweight/obesity; insufficient physical activity and poor nutrition as the major risks and reasons for developing T2DM (Diabetes Australia, 2015). With a rapidly ageing population, these attitudinal responses and limited functional literacy regarding T2DM, indicate a need for a more nuanced approach to health promotion and risk reduction of T2DM in older adults.

6.8 Effectiveness of the AUSDRISK

The unexpected finding of lack of association between *AUSDRISK* HR score levels and biomedically assessed glycaemic levels in older individuals assessed as HR, may be accounted for in part by research findings over the past eight years.

Screening studies for T2DM risk in older individuals by Noble et al (Noble et al., 2011) and Kalyani et al (Kalyani et al., 2013), have shown that risk assessment tools and risk assessment algorithms such as the *AUSDRISK* performed less well in older adult cohorts than for younger and mid-age adult cohorts (Gray et al., 2015, Kalyani et al., 2013, Kegne et al., 2014, Noble et al., 2011). However, at the time of my research the effectiveness of the *AUSDRISK* for T2DM risk assessment in older individuals had not been tested.

The results may also indicate that the combination of risk factors predictive for pre-DM/T2DM in older adults differs from those in middle-aged adults (Ding et al., 2015a, Kalyani et al., 2013), particularly in older age women with a low muscle mass (Caspersen et al., 2015, Kalyani et al., 2014) and these risk factors are either not addressed by the *AUSDRISK,* or the score of *AUSDRISK* risk elements does not reflect the inter-related components of T2DM risk in an older-age cohort (Ding et al., 2015b, Ding et al., 2014).

As a possible correlate of the notion that biochemical markers of T2DM might differ between ages, a recent study by Alva et al (Alva et al., 2017) compared the performance of 4 simple Risk Assessment Tests, against enhanced equations using the 4 Risk assessment tests plus biomedical assessment across 3 different age cohorts – young (18–40 years), middle-aged (45–64 years), and older (65 years and older) US adults to predict T2DM risk. The biomedical tests comprised Fasting Plasma Glucose (FPG); High Density Lipoprotein cholesterol (HDL-C) and Triglyceride levels. They found that the predictive capacity of all 4 risk assessment tests alone was better in middle-aged (45-60 years) than in younger (18-40 years) and older cohorts (65 years plus). Biomarkers were more reliable and important in older age populations than younger (populations) for accurate identification of T2DM risk. As

a result of their findings, Alva et al (Alva et al., 2017) recommended the development and use of age-specific equations for practical tools for T2DM risk stratification.

6.9 Conclusion

Individuals in the older age group are living longer than any previous generation and the healthcare emphasis should be on ensuring they retain a good quality of life and effectively manage age-related conditions (Corriere et al., 2013, Kalyani et al., 2017, Schneider et al., 2016). Routine T2DM screening, particularly for those in the *young-old* age group, with follow-up biomedical assessment for those at HR, and implementation of lifestyle changes and/or medication management for those with established preDM/T2DM, would offer the opportunity to achieve immediate benefits to their quality of life, and reduce the risk of having an undiagnosed hyperglycaemic condition with microvascular, macrovascular complications (Halter et al., 2014), disability (Bianchi et al., 2016, Koye et al., 2017), hospitalisations (Comino et al., 2015), and some cancers (Steele et al., 2015, Twigg et al., 2015). From a positive viewpoint routine T2DM screening would reduce mortality risk (Kristensen et al., 2016, Paprott et al., 2015) from T2DM, and maintain/improve their current lifestyle and independence potentially over the next 15–25 years.

This real-world study implemented and evaluated an innovative community-based T2DM screening to biomedical assessment initiative for *young-old* individuals in Tasmania. As an effective screening strategy, recruitment via mail-out followed by completion to biomedical assessment was shown to be more successful than Direct recruitment via healthcare services. In Australia established national screening initiatives (colon cancer, breast cancer) utilise initial mail-outs for recruitment and reminder systems to increase participation in the *young-old* age group. This approach is familiar to older age individuals and potentially could be implemented for preDM/T2DM screening in the 60–74 years age group. However, results of this study suggest that this (preDM/T2DM screening) may be achieved with greater acceptability and be more effective for *young-old* individuals (60 – 74 years) by the

implementation of a screening system utilising direct blood glucose testing via HbA1c on a regular and routine basis during these years.

Chapter 7. Conclusion, recommendations and future directions

7.1 Introduction

This chapter considers the major findings of this study in the light of current T2DM prevalence figures, research findings and policy directions implemented since this study was completed in 2015. This will include proposals and initiatives for T2DM screening in Australia, particularly for older individuals. Comparisons will be made between the current Australian approach to identifying older adults with undiagnosed T2DM or at HR, and screening and management initiatives in other countries. In the UK, US and European countries the emphasis has moved from screening for established T2DM to screening for early identification and management of elevated blood glucose (EBG) to prevent or slow the progression to T2DM (Aroda et al., 2017, Cefalu et al., 2019, Diabetes Prevention Program Research Group, 2019).

Internationally, a personalised medicine approach, using physiological biomarkers, is being advocated for diagnosis and management of T2DM particularly in the older age group (Alva et al., 2017). Identification of the patho-physiological changes underpinning T2DM, including age of T2DM onset, and differences in biomarkers and their rate of progression, is being advocated as the most effective approach to diagnosis and management of preDM/T2DM by Ahlqvist et al. (Ahlqvist et al., 2018) and Dennis et al (Dennis et al., 2019). This approach is also advocated by the German Diabetes Study Group (Zaharia et al., 2019) for the prediction and early identification and management of T2DM complications.

The American Diabetes Association and the European Society of Endocrinology in collaboration have recently released clinical practice guidelines to identify and reduce risk for both atherosclerotic cardiovascular disease (ASCVD) and type 2 diabetes (T2DM) in individuals at metabolic risk (Rosenzweig et al., 2019). These guidelines emphasise regular screening in adults aged 40–75 years for five metabolic risk factors which are known to increase risk in ASCVD and T2DM. The risk factors are elevated blood pressure; increased

waist circumference; elevated fasting triglycerides; low HDL cholesterol and elevated blood glucose. The guidelines are recommending that individuals who have one or two risk factors should receive regular routine screening (fasting blood tests) every 3 years. Those with three risks or more, are considered to be at metabolic risk, and therefore should be assessed annually, or more, if any of the risk factors is increasing. In addition to the active monitoring, those at metabolic risk should follow a healthy lifestyle and if available, be referred to intensive lifestyle programs.

To reiterate, the primary aim of my research in 2014-15 was to determine the feasibility, effectiveness and acceptability of implementing the *AUSDRISK*, in community-based non-medical healthcare and non-healthcare settings in Tasmania to screen older individuals aged 50 years and over for T2DM and identify those with undiagnosed T2DM or at HR. This targeted screening procedure was in accordance with the *NHMRC Guidelines for Case Detection and Diagnosis of Type 2 Diabetes* (Colagiuri et al., 2009c) for identifying individuals with or at HR for T2DM. These *Guidelines* recommend completing the *AUSDRISK* Assessment Tool as the first step in identifying individuals at High Risk for T2DM, followed by a blood glucose assessment to determine their glycaemic status.

The decision to implement a community-based strategy for this study was based on the NHMRC Guidelines (Colagiuri et al., 2009c) with regard to the suitability of targeted T2DM screening for population groups known to be at HR for T2DM such as the older age group, and to increase the availability of the *AUSDRISK* for self-assessment and health promotion of T2DM. At the time of this study, a fasting blood glucose (FBG) test was recommended. Later as the HbA1c diagnostic test became a funded Medicare item, it was the first test of choice for its higher reliability in that it reflects the integrated blood glucose level over the previous 3 months (D'emden et al., 2012) and has higher specificity than FPG and OGTT (Vistisen et al., 2019). From the viewpoint of participating individuals, the HbA1c test is more convenient as it does not require an 8–12 hours fast prior to testing.

Type 2 diabetes is an age-related disorder (Lee et al., 2017) and older adults are at high risk for the development of T2DM due to the combined effects of epigenetic, genetic, lifestyle and ageing factors. The stimulus for this research was the recognition that the older age cohort is the most rapidly increasing in Tasmania and nationally. Tasmanian data from the *National Diabetes Services Scheme* (NDSS) indicated that the number and percentage of individuals aged 70 years and above being newly diagnosed with T2DM have increased annually over the last 5 years. In Tasmania, 337, or 29.0% of newly diagnosed with T2DM in 2018 were aged 70 years or older, while nationally the number was 16,101, or 25.3% (Australian Government, 2018). Type 2 diabetes has a long latent period (5–10 years) with fluctuating and gradually increasing dysglycaemia prior to the onset of T2DM. If this gradually increasing dysglycaemia had either not occurred in previous years, or was occurring but not identified prior to the individual entering the older years, then to identify the T2DM risk status in the so-called “young-old” age period (60–74 years) (Beard et al., 2016a) would offer the opportunity to prevent progression to T2DM, or alternatively to effectively and appropriately manage an existing but previously undiagnosed T2DM (Ahlqvist et al., 2018, Dennis et al., 2019).

7.1.1 Feasibility of distributing *AUSDRISK* for community-based screening

The research presented in this thesis has shown it was feasible to distribute the *AUSDRISK* both face-to-face (Direct) in community healthcare settings and via a non-health service mail out (Indirect). The initial uptake and completion of *AUSDRISK* was limited but comparable to the initial presentations of screening initiatives internationally (Robson et al., 2016, Stone et al., 2014). Although the Direct presentation of *AUSDRISK* achieved a greater initial completion, it had a poor follow-up rate of High Risk (HR) participants presenting to their GP for biomedical assessment. The Indirect recruitment via mail out achieved a limited take-up rate, but for those assessed as HR, the follow-up rate was higher than for those identified via the face-to-face presentation. The Indirect procedure had no complications associated with impact on time for service delivery experienced by health professionals in the Direct presentation. Overall, a mail-out was superior to invite older age individuals to participate in a

T2DM screening strategy and had the potential for increased participation by providing age-specific T2DM information in invitations, and utilizing reminder notices. This finding is in line with screening strategies currently implemented in Australia, breast cancer screening and colorectal cancer screening, which use mail-outs for recruitment and reminders to individuals in the same age cohort.

7.1.2 Effectiveness of *AUSDRISK*

However as discussed previously the HR score on the *AUSDRISK* was found not to accurately predict those older age individuals at HR who required a follow-up blood glucose assessment to verify their blood glucose status from those older individuals scoring HR who did not require follow-up. Therefore, the *AUSDRISK* did not fulfil its role as an effective first step "filter" in a T2DM screening procedure for the older age cohort. In fact, at the time of biomedical assessment, the *AUSDRISK* results appeared to have "over diagnosed" (Bulliard et al., 2015) the T2DM risk status of this older-age cohort. The blood glucose test results of those at HR (who were subsequently) biomedically assessed, found no HR individual with T2DM; 14.3% HR with elevated blood glucose/preDM, while 85.7% HR were normoglycaemic. Furthermore, there was no significant difference in the HR scores of those with EBG, and those at HR who were found to be normoglycaemic on biomedical assessment. The *AUSDRISK* is based on population level risk predictions for development of T2DM within a 5-year period (Dunstan et al., 2002a) and as such is not designed to take into consideration the complex interactions of risk factors at an individual level (Ding et al., 2015a) nor to identify an individual's precise level of risk and current blood glucose status (which is actually what participants want to know). Therefore, to propose using *AUSDRISK* HR results, as a first stage filter to increase efficiency and reduce cost, appears not to be an appropriate step prior to blood glucose testing for the older age cohort. An argument may be presented that at least the *AUSDRISK* "delineates" between HR and intermediate risk (IR) for T2DM. However as the *NHMRC Guidelines for Case Detection and Diagnosis of Type 2 Diabetes* (Colagiuri et al., 2009c) and *AUSDRISK* do not have recommendations for those

scoring in the IR range to receive a blood glucose test, it is not possible to know the accuracy of this “delineation”.

7.1.3 Acceptability of *AUSDRISK* for community-based screening

Overall, the older adults who participated in this study had knowledge of the modifiable lifestyle risk factors for T2DM, but little knowledge of the complexity and potential severity of risks for T2DM, and no knowledge that older age was a major non-modifiable risk factor. These knowledge barriers were comparable with findings in international research (Eborall et al., 2012, Heidemann et al., 2019). The older age cohort was dependent on their GP for health advice and direction, and were not well-prepared to self-assess their T2DM risk, and self-direct the follow-up actions required if found to be at HR. This lack of diabetes literacy limited their initial and follow-up participation in a screening program. This appears to be an ongoing difficulty. In July 2017, as part of *National Diabetes Week* (*NDW*), *Diabetes Australia* news (www.diabetesaustralia.com.au/news/15424?type=articles) reported that recent research had found that only 5.0% of Australians aged over 40 years had completed an *AUSDRISK* assessment in the previous 2 years, and only 21.0% in the same age range had heard of the *AUSDRISK* assessment. Clearly the unfamiliarity with the *AUSDRISK* and lack of knowledge that increasing age was a major non-modifiable risk factor for T2DM, did not encourage older individuals to investigate their T2DM risk.

7.1.4 Findings and comparisons with international studies

The value of my study was that it showed there were limitations in distribution, acceptability and effectiveness of using *AUSDRISK* at an individual level in an older age cohort. This finding aligns with international research which reported that Risk Assessment Tools were less effective in predicting T2DM risk in older-age cohorts (Alva et al., 2017, Kegne et al., 2014, Noble et al., 2011).

Whilst distribution via mail out was found to be effective, my study did not have the opportunity to increase participation via reminders (phone/mail) as Groenenberg et al.

(Groenenberg et al., 2016, Groenenberg et al., 2015); Robson et al. (Robson et al., 2016) and Bauman et al (Bauman et al., 2016) had found to be essential for maximising numbers of participants. In addition, participation in my study is likely to have been limited by personal barriers of poor functional diabetes literacy and poor perception of actual risk. This lack of knowledge has been reported by many researchers in relation to both the general population and the older age cohort Lavielle and Wacher (Lavielle et al., 2014) Godino et al. (Godino et al., 2014b) and more recently Robson et al. (Robson et al., 2016) and Harte et al (Harte et al., 2017). Poor diabetes literacy and poor perception of T2DM risk had been found specifically in the older age cohort by Adriaanse et al: Gallivan et al; and Heidemann et al (Adriaanse et al., 2008, Gallivan et al., 2009, Heidemann et al., 2019) and was obvious in the responses from HR individuals who participated in the follow-up survey in my study.

The ongoing concern for health service provision, particularly for older adults, is that the older age cohort is living longer and is known to be the cohort at highest risk for T2DM and the actual level of risk and presence of T2DM in many individuals is not being identified before they reach their older years (Australian Government, 2019c). This is at a time in their lives when they are likely to be experiencing a range of illness conditions which make it more difficult to achieve effective management of preDM or T2DM. This scenario was evident from the comments made by HR participants in this study. The Australian Institute of Health and Welfare Diabetes Snapshot (Australian Institute of Health and Welfare (Aihw), 2018) reported there were one million hospitalisations associated with diabetes (principal and/or additional diagnosis) in 2015–16. Type 2 diabetes accounted for 63% of 50,000 hospitalisations with diabetes as a principal diagnosis. There were 1,053,700 hospitalisations with diabetes as an additional diagnosis of which 90% were due to T2DM. Hospitalisation rates for T2DM (30,055 per 100,000), were highest among males 85 years and over (*old-old* years) and in females aged 75-84 years (19,261 per 100,000) in their *mid-old* years. There were 5,000 lower limb amputations during 2015-16, mainly male with 62% aged 65 years and over.

7.2 Prevalence of type 2 diabetes in 2017-18

The recently released statistics from the *Australian Bureau of Statistics* (ABS) *National Health Survey* (AHS): First Results 2017–18 (Australian Bureau of Statistics, 2018) show that 4.9% or 1.2 million people over age of 15 years had diabetes (all types). This finding indicates that the overall rate of diabetes has remained virtually the same since 2014–15. This is the first time in 5 years that the rate of diabetes has stabilised. The prevalence of type 2 diabetes (T2DM) has also remained steady since 2014–15 at 4.4%, with a further 3.1% having impaired fasting plasma glucose (IFG/elevated blood glucose /EBG) which puts them at very high risk for developing T2DM. However, this stability in incidence and prevalence of T2DM is not the finding for the older age cohort aged 60 years and over. The 2017–18 Australian Health Survey highlights that:

> *the rate for T2DM in those aged 65-74 years has increased from 12.5% in 2001 to 15.4% in 2017-18 and for those aged 75 years and over from 11.2% in 2001 to 18.7 % in 2017-18. Males have a higher prevalence than females for T2DM which is indicated in the current rate for males being 18.7% in 65-74 years and 20.7% in those aged 75 years and over. The current rate for females aged 75 years and over is 17.0%. (Australian Bureau of Statistics, 2018).*

So, whilst the overall rate of T2DM has remained steady for individuals up to the age of approximately 60 years since 2014, both the prevalence and incidence of T2DM in older-aged individuals is increasing (Australian Institute of Health and Welfare (Aihw), 2018). This is due in part to those with T2DM living longer but in so doing, the risk for diabetes-related complications increases. Information from *Diabetes Tasmania* (personal communication) indicates that 72.0% of current NDSS registrants with T2DM in Tasmania are in the 60 years and over age group, of whom 44.0% are aged 70 years and over (Australian Government, 2018). The older age cohort has a mix of individuals some with established T2DM and others with newly diagnosed T2DM. The management of the older age cohort with T2DM and preDM is a rapidly growing problem for effective clinical management (Kalyani et al., 2017).

However, the prevalence and occurrence of T2DM in the older cohort is not being communicated to older individuals and not being effectively addressed as an age-related condition by Government and Non-Government organisations.

7.3 Major research findings subsequent to my research in 2014–15

For some time a consensus has been emerging in regard to the pathology of T2DM from it being considered mainly a lifestyle disease, to T2DM being a complex heterogeneous condition involving epigenetic, genetic, ageing and environmental factors (Ahlqvist et al., 2018, Kalyani et al., 2017). This acknowledgement of the heterogeneity and complexity of T2DM and preDM has transformed the recommended approaches for identification and management of these dysglycaemic states from a “one-size-fits-all” to an individualised approach to identify the combined influence of risk factors at the individual level, followed by individualised management, be that lifestyle modification and/or medication, to best address the impact of those risk factors, be they modifiable or non-modifiable (Ahlqvist et al., 2018, Kalyani et al., 2017).

In the last five years, research has clearly demonstrated that, in overweight individuals, T2DM in early stages can be reversed to normoglycaemia via an initial strict weight loss program (initially 800 calories per day for 6-8 weeks) followed by low calorie diet (Taylor et al., 2018b, White et al., 2016) (Lean et al., 2018), (Bodicoat et al., 2017, Taylor et al., 2018a). Studies by the Diabetes Prevention Program Outcome Studies (Diabetes Prevention Program Research Group, 2019) have also shown that early identification of glycaemic dysfunction (notably IGT) with early treatment lifestyle, and/or metformin will significantly reduce onset of T2DM and in some individuals revert to and maintain normoglycaemic levels of blood glucose (Apolzan et al., 2019, Diabetes Prevention Program Research Group, 2019). These studies are among the first to show that having a blood glucose level in the T2DM range is reversible within 2–5 years of diagnosis. Participants included in these trials were aged up to 65 years which makes those individuals in the early years of the “young-old” cohort suitable for this type of intervention. It also implies that those in the *young-old* cohort

would most likely obtain the best results if they were receiving regular blood glucose testing to reveal when they first enter a dysglycaemic state. Research completed by Vistisen, et al. (Vistisen et al., 2019) found that within a 5-year period most people with HbA1c-defined preDM either remained in that state or progressed to T2DM. In contrast to this, people with FPG or 2hr-OGTT-defined preDM frequently reverted from preDM to normoglycaemia. However only those whose preDM status was diagnosed via a 2hour OGTT, had a reduction in future risk for cardiovascular disease if they reverted to and maintained a normoglycaemic state. Initial annual screening (followed by 3- yearly screening), from the date of identification of dysglycaemia for at least five years, would most likely identify the trajectory of the dysglycaemic condition and facilitate appropriate management of whichever pattern of dysglycaemia they were experiencing (Ahlqvist et al., 2018, Dennis et al., 2019, Taylor et al., 2018a). A study by Zucker et al. 2017 (Zucker et al., 2017) which considered the age at first diagnosis of T2DM and mortality, noted that increased risk for mortality was observed at all ages including those aged 75 years and older. However, as noted by Kalyani et al. (Kalyani et al., 2017) when adults over 65 years are first diagnosed with T2DM it is not immediately clear whether the T2DM is “elderly onset” and therefore more likely to have a relatively benign progress of their diabetes condition (Ahlqvist et al., 2018) or whether the T2DM has been long-standing, but undiagnosed.

Implementing these research findings at a clinical level is dependent on the recognition of the complexity of preDM (by differences in diagnostic criteria) and whether preDM is considered a recognised condition to invoke active management or a risk factor for T2DM to be monitored. Recent published research by Njeru et al. (Njeru et al., 2019), has found that preDM is not fully recognised by clinicians in primary care and that education for clinicians on the diagnosis and management of preDM with the aim to revert to normoglycaemia is essential to achieve T2DM prevention and avoid cardiovascular disease complications associated with preDM. Whilst these latest research findings offer a more positive outcome to highlight the benefit of screening and identifying HR for T2DM, the heterogeneity of T2DM

and complexity of identification and effective management of risk for T2DM presents an increasing demand on clinical management (Gray et al., 2016, Kalyani et al., 2017).

Australia lacks a national screening program for identifying preDM/T2DM, with GPs following current guidelines (Colagiuri et al., 2009c, Royal Australian College of General Practitioners, 2018) to pursue an opportunistic approach to implementing a blood test to identify individuals with or at HR for developing T2DM. The results of this study showed that on presentation of a HR score on *AUSDRISK,* most GPs followed NHMRC and RACGP guidelines (Colagiuri et al., 2009c, Royal Australian College of General Practitioners and Diabetes Australia, 2016-18) and recommended a blood test (most likely FPG in 2014/15) to identify preDM/T2DM. The GPs recommended general lifestyle modification measures for those individuals identified with preDM, and advice that they would be monitored but no detailed or personalised lifestyle program, referral for specialist diabetes education nor medication was offered. This would suggest that the impact of preDM and the need and benefit of early intervention was not being fully recognised by GPs in Tasmania at the time of my research (Njeru et al., 2019). Personal communication with accredited diabetes educators in Tasmania would suggest that unfortunately little has changed over recent years.

7.4 Australian national policy directions relating to T2DM

The *National Diabetes Strategy* (NDS) 2016–2020 (Australian Government, 2015) was developed by the *National Diabetes Strategy Action Group (NDSAG*) in 2015 and implemented from 2016 (after completion of my field research).

NDS Goal 1 addressed issues to reduce the number of people developing T2DM – taking a whole-of-population approach to encourage and enable healthier lifestyles.

NDS Goal 2 aimed at promoting earlier detection T1DM and T2DM to facilitate earlier diagnosis and earlier treatment for all forms of diabetes. In relation to earlier detection of T2DM the following initiatives were recommended (Australian Government, 2015):

- Establish a nationally coordinated detection program to identify high-risk individuals using the *AUSDRISK* screening tool.
- Establish multiple avenues for the dissemination of *AUSDRISK*, using Primary health networks, community health centres, community pharmacies, optometrists, dentists and online health services in state and federal health departments.
- Promote increased use of the *AUSDRISK* screening tool among all age groups – with the acknowledgement that this may require calibration of scoring on the *AUSDRISK* tool for different age ranges.
- Integrate the *AUSDRISK* screening tool with risk assessment for other chronic conditions, including absolute cardiovascular and kidney disease risk, such as has been achieved in the UK with the *National Health Service (NHS) Health Check program* (Robson et al., 2016) in primary care.
- Improve the health literacy of the community with particular reference to risk for T2DM – both modifiable risk (lifestyle) and non-modifiable (age and genetic).
- Educate primary health care practitioners about who should be screened.
- Review biomedical screening methods (e.g. the use of HbA1c in the screening algorithm procedure).

The goals of the National Diabetes Strategy 2016–2020 are wide ranging and ambitious. Four of the initiatives involve utilizing the *AUSDRISK.* In the light of the findings of this research, it would appear appropriate that a National Diabetes Strategy (NDS) specifically for older individuals be developed, or at least the current NDS amended to reflect the particular issues for older adults, particularly with reference to utilisation of the *AUSDRISK* in screening and instead implement regular direct HbA1c testing for all individuals aged 60 – 74 years within a nationally co-ordinated T2DM screening system.

In relation to the NDS Goal 2, three major clinical initiatives which have the potential to impact on the earlier detection and effective management of preDM/T2DM have been

introduced, and further initiatives are in the planning phase. All initiatives include and require an established regular and replicable screening system supporting the screening/data collection initiatives.

7.4.1 Clinical initiatives introduced as part of the NDS 2016–2020

1. a *diagnostic HbA1c test for T2DM* (*Medicare* item 66841) which may be performed once per year.

2. the *My Health Record* – a collated and up-to-date patient record of all services received in all health sectors.

3. *Heart Health Check* (*Medicare* item 699) for individuals aged 45 years and over considered by their GP to be at risk for CVD events – once per year.

7.4.1.1 HbA1c diagnostic test for T2DM (Medicare item 66841)

The commencement of a Medicare funded annual diagnostic HbA1c test (*Medicare* item 66841) for asymptomatic individuals considered to be at HR for T2DM by their GPs was first introduced in November/December 2014 but not widely used at the time of my field research. The patient criteria for using the diagnostic HbA1c test are either having (i) a medical condition or ethnic background associated with high rates of type 2 diabetes, or (ii) an Australian type 2 diabetes risk (*AUSDRISK*) score of 12 or greater, placing them at increased risk of diabetes. Introduction and standardisation of blood glucose testing using HbA1c as both a T2DM diagnostic and monitoring test (Medicare items 66551, 66554 or 73840) has facilitated ease of blood glucose testing by using a non-fasting test and having rapid results which reflect average blood glucose level for the previous 3 months testing. Confirmatory testing may then be implemented if the HbA1c test is “borderline”. (Colagiuri, 2015); (Lee et al., 2016) This direct blood glucose testing approach overcomes the problem of initially assessing the 5-year risk for developing T2DM via the *AUSDRISK*, which older age adults have found very confusing. The potential to access HbA1c diagnostic screening annually overcomes the issue of irregular opportunistic screening (Colagiuri, 2015). For example, in

older people the annual diagnostic HbA1c test could be initially be implemented every 1–3 years between 60–74 years for non-diabetic asymptomatic individuals, along the lines of the NHS Health Check in UK (Martin et al., 2018, Robson et al., 2016). This would provide an opportunity for early detection of dysglycaemia within a system which would become familiar to older individuals who would relate to this as a "normal procedure" – an important factor as indicated by participants in the NHS Health check program (Usher-Smith et al., 2017). In this way all elements of feasibility, effectiveness and acceptability in a screening program would be covered.

7.4.1.2 My Health Record

In December 2018, the Australian Government introduced the *My Health Record* (https://www.myhealthrecord.gov.au). All Australians will be recorded on the digital *My Health Record* system but be able to "opt out" should they wish. Current concerns are in regard to individual privacy and accuracy of health service reporting versus the convenience and benefits to patients of access by patients, GPs, hospitals, and other health professionals of all the patient's healthcare records and attendances. As at June 2019 close to 90.0% were recorded on the *My Health Record*. Recent media reports suggest that it will take time for this initiative to be established.

Since July 2018, *Diabetes Australia* has been promoting the benefits to people with diabetes (all types) of having their health information recorded on the *My Health Record*. People with diabetes often attend a wide range of health services and there is great benefit in having all the information available to all health professionals providing those services. It is unclear whether people with elevated blood glucose (EBG), that is at HR, will have this recorded annually in order to monitor the increase or reversion to normal levels in their initial elevated blood glucose levels. If such a database were developed and found to be cost-effective, re-test HbA1c reminder notices could be linked to this information in the *My Health Record* and sent annually to those who had previously recorded EBG or had an increased HbA1c result. In addition, there would appear to be potential for all individuals aged from 60–74 years (high

non-modifiable risk) to have a notification generated via the *My Health Record* to attend their GP every 1-3 years for an HbA1c test using the Medicare subsidised diagnostic HbA1c code. Potentially, the *My Health Record* could provide the system for early identification of preDM/T2DM and provide systematic monitoring of those older individuals who remain "at risk for T2DM" with elevated blood glucose. Irrespective of which health services implemented a blood glucose test, the results would be recorded centrally and any pattern of increasing blood glucose level moving towards the T2DM range could be identified early. Such a database could provide a longitudinal record for blood glucose levels and identify the current situation of each individual, for example, showing EBG progress to T2DM; or remaining stable with EBG; or return to normoglycaemia having had lifestyle and/or medication management of their EBG. All information could be linked back to the patient's record available for both patients and health professionals to access.

7.4.1.3 Heart Health Check (Medicare item 699)

In April 2019, the Australian Government announced the government-funded *Heart Health Check* (*Medicare* item 699)(Australian Government, 2019a) for all individuals (aged 45 years and older) considered by their GP to be at risk for CVD events. This Check can be implemented once every 12 months. One of the eligibility criteria for this health check is "diabetes status". In order to establish this, a blood glucose test should be performed. Therefore, by default, this program may provide a system for regular blood glucose measurement and monitoring.

Professional attendance for a heart health assessment by a general practitioner at consulting rooms lasting at least 20 minutes and must include:

a. collection of relevant information, including taking a patient history that is aimed at identifying cardiovascular disease risk factors, including diabetes status, alcohol intake, smoking status, cholesterol status (if not performed within the last 12 months) and blood glucose
b. a physical examination, which must include recording of blood pressure

c. initiating interventions and referrals to address the identified risk factors

d. implementing a management plan for appropriate treatment of identified risk factors and

e. providing the patient with preventative health care advice and information, including modifiable lifestyle factors with appropriate documentation.

The rationale for, and consideration of, a Heart Health Check for individuals aged 45 years and older considered to be at risk for CVD events appears to be along the lines of the *NHS Health Check programme* (Martin et al., 2018). A report by Martin et al indicates that after 8 years of implementation of the *NHS Health Check programme*, 45.0% of those invited had attended. Although the number of individuals completing the *NHS Health Check programme* was initially lower than expected, increased publicity and communication on the purpose of the programme has resulted in year-on-year improvement in attendance. This has led to improved outcomes on the previous opportunistic approach used by UK GPs in the National Health Service. From the viewpoint of the age of participants who attended, the highest rate of completion was shown to be for older individuals and females which would lend support to a similar implementation of a *National Health Check programme* in the 60–74 age group in Australia (Martin et al., 2018, Robson et al., 2016). A recent review undertaken on the *NHS Health Check programme* (Mytton et al., 2018) to assess the current and potential health benefits of the *NHS Health Check programme* also noted that the benefits were greatest for those from disadvantaged areas, thus the overall benefit of the program was reducing health inequalities.

7.5 Recent Australian T2DM screening studies identification of T2DM and preDM

The NDS Goal 2 to establish a nationally coordinated detection program to identify HR individuals using the *AUSDRISK* screening tool has not yet been implemented. However, there have been a number of T2DM screening programs, some using *AUSDRISK* and others using direct implementation of a diagnostic HbA1c test.

7.5.1 Community-based screening for T2DM

A nationwide pharmacy-based T2DM screening program in 340 community pharmacies using *AUSDRISK,* with or without a follow-up HbA1c blood glucose test, was commenced in 2017 (Krass et al., 2017). All states and territories were represented with participating pharmacies. Eligible clients were those aged 35–74 years who had not had a test for T2DM in the previous 12 months. There was high variability in numbers of participating clients and some pharmacies identified no individuals with T2DM. As yet no formal report has been published, although a short report was made available through the *Australian Doctor* magazine (Saxena, 2018). The Pharmacy Diabetes Screening Trial protocol (Krass et al., 2017) utilised 3 variations of *AUSDRISK* presentation to individuals, either the *AUSDRISK* alone, *AUSDRISK* followed by a point-of-care HbA1c test or *AUSDRISK* followed by a point-of-care blood glucose test. Over 14,000 customers were screened and 136 cases of T2DM (approximately 1%) were identified. The cost per case of T2DM identified was estimated to be $8217.00, which included costs associated with conducting the program. No details were available on identification of individuals (and their age) with preDM. The results of this screening program would appear to support the findings in my research with concerns regarding feasibility, acceptability and effectiveness of *AUSDRISK* in identifying people with or at HR for T2DM.

7.5.2 T2DM screening in an acute care hospital and primary care practices in Western Sydney, New South Wales, Australia

This research on screening for T2DM in acute care (hospital) and primary care health (GP) services commenced in 2016. The rationale for the research was based on the under-recognition of T2DM in individuals, and impact of this situation on the health services in a known “hot spot” for T2DM in Western Sydney. This initial research was followed by an analysis of the prevalence and management of T2DM in cardiology inpatients at Blacktown-Mount Druitt Hospital in Western Sydney by Bishay et al. (Bishay et al., 2018). The background to the outpatient study was recognition that two-thirds of individuals presenting to the emergency department in Western Sydney had high blood glucose levels which

accelerated their risk for cardiovascular disease. The study by Bishay et al also showed that undiagnosed T2DM was prevalent and neglected in cardiology patients. In 2019, Meyerowitz-Katz et al. collated the results of screening for T2DM in both acute care at the ED at Blacktown Hospital Western Sydney (BHWS) and 11 general practices in Western Sydney Primary Health Network (PHN). The purpose was to examine preDM and T2DM rates using HbA1c testing for patients attending a hospital ED or a General Practice in the same local suburban area.

7.5.2.1 Emergency Department Blacktown Hospital Western Sydney

The study design comprised an initial random blood glucose (RBG) test for all adult patients attending ED, followed by HbA1c testing if RBG >5.5mm/L. The study was initially over a 6-week period (Hng et al., 2016) and then extended to 2 years (Meyerowitz-Katz et al., 2019). The research methodology designated that an HbA1c test be included in addition to other ordered blood tests unless any of these following exclusions were present – (1) the individual is <18 years (2) HbA1c test had been previously measured within the last 3 months (3) appropriate blood sample was not available or adequate. A total of 55,568 individuals were tested for T2DM in the ED. Results showed that 17.3% had T2DM (based on HbA1c of either = >6.5% or a prior diagnosis); and 30.2 % had preDM. Among those identified with T2DM, 32.2% were previously undiagnosed.

7.5.2.2 T2DM screening in general practices, Western Sydney

In the General Practice arm of the study, GPs added HbA1c testing for patients undergoing routine blood tests (initially over a 6-week period, but extended to a maximum of 11 months). This procedure was close to the opportunistic approach used by many GPs, but in this study, it was part of an established research system. Results from the GP checks showed that of the 6,000 individuals tested, 26.6 % had preDM and 17.4% had T2DM. During the trial period in GP practices the rate of diagnosed T2DM rose from 8.9% to 11.0%.

The *AUSDRISK* was not used to first identify HR (as recommended by Guidelines) instead direct biochemical assessment using HbA1c was implemented (Bishay et al., 2018, Hng et al., 2016, Meyerowitz-Katz et al., 2019). The two arms of the study (ED and GP practices) found that in the Western Sydney area, HbA1c testing for T2DM in ED and GP practices revealed similar results for T2DM prevalence (17.3% in ED and 17.4% in GP) across different areas of the health system (Meyerowitz-Katz et al., 2019). In comparison to the community-based Pharmacy Study (Krass et al., 2017), the ED/GP study used a targeted approach, addressing those who presented with some form of ill-health and identified a significantly higher number of those with or at HR of T2DM than those identified implementing AUSDRISK in community-based screening via pharmacies or had been found in my community-based research for older age individuals.

The Western Sydney screening studies identified the effectiveness of implementing an HbA1c test (as part of a screening research system) to screen large numbers of adults to identify those with or at HR for T2DM. Based on the findings of my research, where the participants had great difficulty comprehending the concept of “T2DM risk” without a diagnosis, the immediacy of the blood glucose test result (without the need to understand T2DM risk) would likely appeal to most participants. However, without a regular repeated screening program and data recording there would be no ability to identify progressive dysglycaemia and intervene prior to development of T2DM.

7.6 Changes in early identification and early management of prediabetes

Internationally, research findings are promoting greater emphasis on identification and treatment (with lifestyle intervention and/or metformin) of preDM which is not a benign condition as it increases the risk of cardiovascular disease. This change in the direction for T2DM prevention by early identification and management of preDM associated with increasing age, overweight and obesity (Apolzan et al., 2019, Herman et al., 2017) is seen by many researchers as the only way to prevent or reduce the impact of T2DM. Whilst lifestyle

initiatives have been found to be effective in achieving weight loss and reduction in blood glucose levels it is acknowledged that it is very difficult to maintain the level of lifestyle interventions that will gain and maintain an effective outcome (Aroda et al., 2017, Cefalu et al., 2019). In older individuals, the level of physical activity may be compromised by co-morbidities such as musculo-skeletal limitations, including arthritis, and loss of muscle mass and strength (sarcopaenia) (Kalyani et al., 2015, Kalyani et al., 2014). Therefore, greater emphasis is being placed on introducing a combined approach of lifestyle and medication to maintain weight loss and normal blood glucose levels for those with EBG particularly impaired glucose tolerance (IGT) (Lean et al., 2018, Taylor et al., 2018b) (Sussman et al., 2015). However, this approach has not been endorsed by a recent Cochrane Review on the development of type 2 diabetes mellitus in people with intermediate hyperglycaemia (Richter et al., 2018). The rationale being that as the intermediate hyperglycaemia and T2DM may transition between stages, GPs should give careful consideration before implementing active medication management. Whatever the clinical decision, it can only be made on the basis of regular screening and monitoring, which is the rationale for early identification of glycaemic status of individuals known to be at HR for T2DM. In view of the increasing prevalence and occurrence of T2DM in the older age cohort, this group should be targeted for early inclusion in a system of regular screening and active management if required.

Asymptomatic individuals should be screened every 3 years. Individuals with preDM should be screened annually as should individuals with other metabolic risks. Therapeutic management would include both lifestyle and medical/pharmacological intervention as required. This comprehensive approach would provide a regular system of screening and management “personalised” to each individual’s therapeutic needs (Apolzan et al., 2019).

7.7 AUSDRISK

In this time of personalised medicine, the *AUSDRISK* appears not be sufficiently precise for identifying those older age individuals who are at HR for progressing to T2DM, from those in the same age range, who are assessed as HR, but are not at risk for progressing to T2DM.

This is supported by results of my research showing that 85% of those assessed as HR by the *AUSDRISK* were normoglycaemic the at time of biochemical assessment. In addition, there was no significant difference in the *AUSDRISK* scores between those at HR, but normoglycaemic on biomedical assessment, from those at HR who were biomedically assessed as having an elevated blood glucose level. Both these findings would indicate that the *AUSDRISK* scores do not differentiate between those who require further biomedical assessment from those who do not. The finding that 85% of those assessed as HR were normoglycaemic on biomedical assessment makes it difficult to provide specific advice to the older age participant that is not personally confusing. Although the *AUSDRISK* is a predictor of T2DM risk over a 5-year period, rather than a diagnostic tool, for the older participant the result suggests that the *AUSDRISK* score "overdiagnoses" (Bulliard et al., 2015) the older individual's T2DM risk. The most effective system for identification of those older individuals at HR (preDM) for T2DM would be along the lines of the *NHS Health Check* with direct regular/repeated implementation of a biochemical test on a 1–3 year basis for older individuals aged between 60–74 years (Martin et al., 2018, Robson et al., 2016).

The *AUSDRISK* has been compared and validated with other risk assessment tests for predicting T2DM risk at a population level (Noble et al., 2011) with acknowledgement that the prediction is most accurate in the mid-years rather than younger or older (Noble et al., 2011). If *AUSDRISK* is not clinically effective for assessing older individuals for T2DM risk, it should be more actively utilised for health promotion and risk assessment for those aged under 60 years where the balance of modifiable and non-modifiable risk factors is more equitable and where HR participants can act on the modifiable risk factors to reduce their overall risk for T2DM.

As a result of the findings in this study I submit the following recommendations, with the acknowledgement that these recommendations, cover a wide range of initiatives and would depend on many Government and non-Government organisations for implementation. I hope the findings in my study encourage these organisations to consider and implement the

recommendations for the benefit of the health of older age Australians and the community in general.

7.8 RECOMMENDATIONS

The findings of my research would strongly support the overall recommendations in the National Diabetes Strategy (NDS) 2016-2020 and in particular the objectives outlined in Goal 2 of this Strategy (pages 160 – 161). But my findings do not support the approach to T2DM screening of one-size-fits-all in the use of *AUSDRISK.* Reference has been made for calibrating the *AUSDRISK* to more effectively identify HR in those of different ages (Lee et al, 2018).

Recommendation 1.

My findings would suggest that the *AUSDRISK* would be best utilised for risk assessment of T2DM in individuals under the age of 60 years. That is, in the mid-years where Risk Assessment Tools have been shown to be more accurate in prediction (Lee et al, 2018. Alva et al., 2017, Noble et al., 2011). The age range 40–60 years (and younger) is the period where the impact of T2DM risk is related to a greater extent to lifestyle than age and where participants have the opportunity to act to seek biomedical assessment if found to be at HR and reduce their risk for cardiometabolic conditions.

Recommendation 2.

My findings would support implementation of a multi-condition screening program along the lines of the *NHS Health Check programme* which would encompass screening pertinent to T2DM and cardiovascular conditions.

This national program could be conducted along the lines of the Australian breast cancer and colorectal cancer screening programs with publicity, initial notification and reminder notices to facilitate participation. The program would include 1–3 yearly T2DM screening (depending

on individuals' last recorded glycaemic status); and initially use an HbA1c test with confirmatory testing if required.

Recommendation 3.

The aim of the screening program for identifying older adults (60 – 74 years) would be to identify hyperglycaemia at the preDM stage and introduce management to revert the hyperglycaemic condition to normoglycaemia or effectively manage the hyperglycaemia to prevent complications.

Such a program would also address the need for publicity, accurate information, initial and reminder notices so that T2DM screening becomes "usual practice" for older persons. In so doing, it would avoid the targeting of 'individual blame' for so-called poor health practices. These negative behavioural components were frequently noted by older individuals who participated in my research.

My findings also indicated that the older age cohort finds primary care medical management to be an acceptable and familiar system. The participants' confidence in a system is essential to participation in regular screening (Usher-Smith et al., 2017).

Recommendation 4.

Guidelines are required to direct these changes in practices so it is timely to review the *NHMRC Evidence based Guideline for Case Detection and Diagnosis of T2DM* (2009) to reflect the major findings in recent international research on the heterogeneity of T2DM and the benefit of screening for risks associated with preDM,T2DM and cardiovascular disease. This review would align and provide consistency with the current review of the *RACGP Guidelines for Prevention and Management of Diabetes 2016–18.* It is hoped that both sets of *Guidelines* will reflect T2DM and its dysglycaemic precursors as an age-related chronic condition. In addition, to address the complexity of identification and the essential ongoing management of dysglycaemic states to prevent the onset of complications, and reduce

comorbidities such as dementia and frailty in an older age cohort, which is rapidly increasing in numbers and longevity.

With the introduction of the *My Health Record* database, there is an opportunity to link patient pathology tests (such as HbA1c, FBG, OGTT) and have current test results across Acute Care hospitals and Primary Care GP practices.

Recommendation 5.

Finally, the general public needs to know of recent advances in diagnosis and management of preDM/T2DM and learn that these conditions are reversible if identified in the early stages of dysglycaemia. Diabetes websites such as *Diabetes Australia* (Diabetes Australia, 2017a) and their state branches should promote the complexity of T2DM by recognizing the epigenetic, genetic, lifestyle and age-related risk factors for T2DM– with the aim to promote this complexity and reduce the popular and prevailing attitude towards “personal blame” associated with poor lifestyle choices for the onset of T2DM (Browne et al., 2017, Browne et al., 2013, Ventura Ad et al., 2016). This approach is particularly important for older individuals with late onset preDM/T2DM who may well have been following a healthy lifestyle which, for many years has compensated for non-modifiable risk factors. Similarly, it is important that individuals feel confident (not blame) to seek assistance to reduce their risk for preDM/T2DM.

7.9 STRENGTHS & WEAKNESSES

This research was conducted in 2014-15 in 2 community-based health services and via a non-health statewide mail-out of the Seniors Card to older adults over the age of 60 years. Distribution of the AUSDRISK (plus information for completion) utilised existing systems, (other than medical) for distribution. Whilst the methods of distribution were feasible, interest in completing the AUSDRISK was low. In the older age cohort approximately, half scored Intermediate Risk (IR) and half High Risk (HR). According to the AUSDRISK recommendations only those scoring HR are advised to attend their GP for a biomedical

assessment. This would be the case in all T2DM screening studies using AUSDRISK. Of those who completed the AUSDRISK and scored High Risk (HR) the positive predictive value of the AUSDRISK HR score was zero. At the time (2014-2015) this result was unexpected and thought possibly to be due to a small sample size. However, Noble et al, 2011 had noted that Risk Assessment Tests were more effective in accurately identifying T2DM risk in individuals aged 40 - 60 years rather than those of older age. Subsequently the Pharmacy Diabetes Screening Trial in Australia by Krass et al 2017, using the AUSDRISK found a 1.0% detection of T2DM in a large study of 14,000 participants. Irrespective of participant numbers Community – based screening using AUSDRISK appears not to be effective or cost-effective.

The information provided by the HR participants who attended their GP for a biomedical assessment, and pre-arranged to complete a survey after attending their GP and establishing their T2DM status, was invaluable. A large proportion had never heard of the AUSDRISK, and this situation appears not to have changed judging by the results from the Diabetes Australia, 2017. Most HR respondents relied on their GPs for information and direction for preventative care. So, the fact that there was a poor take-up response reflects the need to utilise a familiar process to engage older age persons.

Subsequent research in Australia within primary health and acute care (Bishay et al., 2018, Hng et al., 2016, Meyerowitz-Katz et al., 2019) using direct biomedical assessment (HbA1c) is more effective. The apparent negative results from my study and other community-based T2DM screening in Australia would appear to support the direction of T2DM screening being best utilised within primary health and acute care. Hence my recommendation for implementation of a system along the lines of the NHS Health Check programme and close links with acute care medicine, particularly for older adults.

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Appendix 1

Australian Government
Department of Health and Ageing

What is type 2 diabetes?

Type 2 diabetes is a chronic (long-term) disease marked by high levels of sugar in the blood. It occurs when the body does not produce enough insulin (a hormone released by the pancreas) or respond well enough to insulin. Type 2 diabetes is the most common form of diabetes. There are approximately 1 million people with type 2 diabetes currently. This figure is expected to increase significantly in the coming years.

People with diabetes have a higher risk of developing heart disease, stroke, high blood pressure, circulation problems, lower limb amputations, nerve damage and damage to the kidneys and eyes.

Risk factors

Many Australians, particularly those over 40, are at risk of developing type 2 diabetes through lifestyle factors such as physical inactivity and poor nutrition. Family history of diabetes and genetics also play a role in type 2 diabetes.

What can you do to lower your risk of developing type 2 diabetes?

Your lifestyle choices can prevent or, at least, delay the onset of type 2 diabetes.

You cannot change risk factors like age and your genetic background. You ***can*** do something about being overweight, your waist measurement, how active you are, eating habits, or smoking.

If there is type 2 diabetes in your family, you should be careful not to put on weight. Reducing your waist measurement reduces your risk of type 2 diabetes.

By increasing your physical activity and improving your eating habits you can lower your risk. Eat plenty of vegetables and high fibre cereal products every day and use a small amount of fats and oils. Monounsaturated oils, such as olive or canola oil, are the best choice.

You can have type 2 diabetes and not know it because there may be no obvious symptoms.

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

How do you score?

The Australian Type 2 Diabetes Risk Assessment Tool was developed by the Baker IDI Heart and Diabetes Institute on behalf of the Australian, State and Territory Governments as part of the COAG initiative to reduce the risk of type 2 diabetes

Current from: May 2010

(811100)

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

1. Your age group

Under 35 years	☐	0 points
35 – 44 years	☐	2 points
45 – 54 years	☐	4 points
55 – 64 years	☐	6 points
65 years or over	☐	8 points

2. Your gender

Female	☐	0 points
Male	☐	3 points

3. Your ethnicity/country of birth:

3a. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?

No	☐	0 points
Yes	☐	2 points

3b. Where were you born?

Australia	☐	0 points
Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe	☐	2 points
Other	☐	0 points

4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)?

No	☐	0 points
Yes	☐	3 points

5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness, during pregnancy)?

No	☐	0 points
Yes	☐	6 points

6. Are you currently taking medication for high blood pressure?

No	☐	0 points
Yes	☐	2 points

7. Do you currently smoke cigarettes or any other tobacco products on a daily basis?

No	☐	0 points
Yes	☐	2 points

8. How often do you eat vegetables or fruit?

Every day	☐	0 points
Not every day	☐	1 point

9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?

Yes	☐	0 points
No	☐	2 points

10. Your waist measurement taken below the ribs (usually at the level of the navel, and while standing)

Waist measurement (cm) ☐

For those of Asian or Aboriginal or Torres Strait Islander descent:

Men	Women		
Less than 90 cm	Less than 80 cm	☐	0 points
90 – 100 cm	80 – 90 cm	☐	4 points
More than 100 cm	More than 90 cm	☐	7 points

For all others:

Men	Women		
Less than 102 cm	Less than 88 cm	☐	0 points
102 – 110 cm	88 – 100 cm	☐	4 points
More than 110 cm	More than 100 cm	☐	7 points

Add up your points ☐

Your risk of developing type 2 diabetes within 5 years*:

☐ ***5 or less: Low risk***
Approximately one person in every 100 will develop diabetes.

☐ ***6-11: Intermediate risk***
For scores of 6-8, approximately one person in every 50 will develop diabetes. For scores of 9-11, approximately one person in every 30 will develop diabetes.

☐ ***12 or more: High risk***
For scores of 12-15, approximately one person in every 14 will develop diabetes. For scores of 16-19, approximately one person in every 7 will develop diabetes. For scores of 20 and above, approximately one person in every 3 will develop diabetes.

**The overall score may overestimate the risk of diabetes in those aged less than 25 years.*

If you scored 6-11 points in the AUSDRISK you may be at increased risk of type 2 diabetes. Discuss your score and your individual risk with your doctor. Improving your lifestyle may help reduce your risk of developing type 2 diabetes.

If you scored 12 points or more in the AUSDRISK you may have undiagnosed type 2 diabetes or be at high risk of developing the disease. See your doctor about having a fasting blood glucose test. Act now to prevent type 2 diabetes.

Tasmanian Health Organisation – South

GPO Box 1061, HOBART TAS 7001 Australia
Ph: (03) 6233 8308
Web: www.dhhs.tas.gov.au

Tasmanian Government

Contact: Fred Howard
Phone: (03) 6233 6796
Facsimile: (03) 6233 6926
E-mail: fred.howard@dhhs.tas.gov.au
File:

Assoc. Prof Kate Macintyre
School of Medicine
University of Tasmania
Level 1 Medical Science 1
17 Liverpool Street
HOBART TAS 7001

Dear Assoc. Prof Macintyre

Subject: HOO13490

Thank you for your recent letter dated 3 December 2013 formally requesting to conduct a research trial to implement the AUSDRISK assessment tool as part of the initial assessment for new patients attending the Clarence Integrated Care Centre.

As you may already be aware the Integrated Care Centre program is focused on the development of facilities that support an integrated approach to the prevention and management of complex and chronic disease. To have implemented the AUSDRISK assessment tool as part of the initial assessment of new patients would add great value to the centre's role in the prevention and management of one of the significant chronic diseases. Consequently I would welcome the centre being part of the research trial.

I note from your letter that Liz has been liaising with my Deputy Fred Howard. I would encourage Liz to continue working with Fred as he is responsible for the Integrated Care Centre Program i.e. both the capital and service model development. Fred will organise Liz's introduction to the relevant service managers/clinicians to help facilitate full consultation.

Meanwhile thank you for the opportunity for the centre to be involved in the trial. Please feel free to contact either me or Fred if you wish to discuss any aspect of the centre's involvement in the trial

Yours sincerely

Bruce Edwards
Group Manager

24 January 2014

Cc Liz Bingham
Fred Howard

FW: Diabetes Risk Assessment Study

Elizabeth Bingham

Fri 16/01/2015 11:49 AM

Last year when you signed in for an appointment at the front desk of Clarence Integrated Care Centre, you participated in a diabetes risk assessment study being conducted by the University of Tasmania School of Medicine. You completed the AUSDRISK type 2 diabetes risk assessment brochure and scored in the high risk range.

Thank you for signing a yellow form to indicate you were willing for the School of Medicine to receive your AUSDRISK Diabetes Risk assessment score (but not your name) and that a university researcher could contact you at a later date.

This email is in relation to your AUSDRISK Diabetes Risk assessment. We would appreciate you answering the following 8-9 YES/NO questions in this survey to help us understand the effectiveness of the AUSDRISK.

CLICK ON THIS LINK TO ACCESS THE SURVEY: https://www.surveymonkey.com/s/3BHX9NR

Thank you for participating in the diabetes risk assessment study being conducted by the University of Tasmania's School of Medicine. Your time and interest is greatly appreciated.

Liz Bingham
Candidate, Doctorate of Health
University of Tasmania School of Medicine
Email: bethuneb@utas.edu.au

AUSDRISK SURVEY

Clarence Integrated Care Centre

The Clarence Integrated Care Centre is **introducing the AUSDRISK assessment for all new patients** aged 18 years and over, to help them find out their risk for developing type 2 diabetes. This condition has very few symptoms or warning signs. It is important to know your diabetes risk.

AUSDRISK is not a diagnostic test for type 2 diabetes but it can show whether you would benefit from being assessed for type 2 diabetes by a GP/medical practitioner and receiving medical advice.

The University of Tasmania, School of Medicine is assisting CICC to introduce the AUSDRISK, so you will be asked to give your consent to participate in this study.

Participation is voluntary. Please read the Consent Form on the back of this Information sheet.

If you have already been medically diagnosed with type 1 diabetes or type 2 diabetes

- **DO NOT complete the AUSDRISK.**
- **Place a tick to indicate which diabetes diagnosis you have and approximate date of diagnosis, and return this form to the staff member:**

Type 1 diabetes .....year diagnosed..... **Type 2 diabetes** .....year diagnosed .....

INSTRUCTIONS TO COMPLETE THE AUSDRISK:

- You may obtain help to complete the AUSDRISK today at the Clarence Integrated Care Centre from an adult family member, friend or your therapist or nurse.
- Answer ALL the AUSDRISK questions.
- Measure your waist and record your measurement (in cms) on the AUSDRISK.
- Tick the small box to indicate the range for your waist measurement.
- ADD UP all the points (in the small boxes ticked).
- Write your final score in the last large box on the AUSDRISK form.
- **People who score in the High Risk range are advised to see their GP/medical practitioner to be assessed for diabetes.**

KEEP YOUR COMPLETED AUSDRISK FORM and note the ADVICE provided for your AUSDRISK score.

Are you willing to participate in this study? Please write your results in the box below.

Print and sign your name on the Consent Form (over page)

Write your final AUSDRISK score here .....

Your gender (circle whichever is correct) FEMALE MALE

Your Age .....years

Has either of your parents, brothers or sisters been diagnosed with type 1 or type 2 diabetes? Please circle whichever is correct: YES NO

Did you need assistance to complete AUSDRISK? YES NO

CONSENT FORM (for all participants)

1. I have understood the instructions and completed the AUSDRISK and written my details requested on page 1 of the 'Information Sheet'.
2. I consent to my AUSDRISK score and details (gender, age, family history of diabetes) on this sheet being made available to the University of Tasmania, School of Medicine.
3. I understand the AUSDRISK is not a diagnostic test and that if I score in the High Risk range I will be advised to see a medical practitioner for a medical assessment. Scoring at High Risk does not mean I have diabetes.
4. I understand that if I score in the High Risk range I will be invited to participate in a follow-up study. This will involve volunteering a very short amount of my valuable time for either a short telephone interview by a UTAS researcher or completing a short email survey.
5. I understand that participating in the follow up component of this study is voluntary.
6. I understand that all my data and details will be securely stored on the University of Tasmania premises for seven years, and will then be destroyed.
7. I agree that research data gathered from me for the study may be published, provided that I cannot be identified as a participant.
8. I understand I may withdraw at any time without any effect, and I may request that any data I have supplied to date be withdrawn from the research.
9. **If you agree to have your answers made available to the UTAS, School of Medicine, please sign this Consent Form, check you have completed the AUSDRISK and filled out the details on the front page.**

Return this Information sheet completed to your nurse or therapist.

NAME.....

SIGNATURE.....DATE:.....

Thank you for your participation

If you scored in the High Risk range (12 points or more) UTAS, School of Medicine would like to contact you again 5-6 weeks after you completed the AUSDRISK.

Please circle: **AGREE or DO NOT AGREE** to receiving a telephone call or email from a University of Tasmania researcher to participate in a short follow-up telephone interview or completing a short email survey. Participation in the follow-up study is voluntary. If you agree, please provide your preferred way for UTAS to contact you.

Phone number (mobile or landline) .....

Email address: .....

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au

Implementation of AUSDRISK Assessment Tool at Clarence Integrated Care Centre

Role of Health Professional staff

Ask for the AUSDRISK documentation and thank the patient for completing it – or assist the patient if they have been unable to complete it. *Record the need for assistance in the results box on the front of the yellow form.*

State that the Clarence Integrated Care Centre is conducting a trial for the AUSDRISK to be part of every new patient assessment. As this is a new initiative for CICC, the University of Tasmania (UTAS) is assisting to monitor and evaluate the introduction of the AUSDRISK.

State that the AUSDRISK provides an assessment of the patient's risk for developing type 2 diabetes. It is NOT used to diagnose type 2 diabetes, that can only be done by a medical practitioner.

Check that all the AUSDRISK questions have been answered.

If not, offer assistance to complete the AUSDRISK

Check that the patient's waist has been measured. If not, please use the tape measure (supplied) and ask the patient if you may take a waist measurement in order to obtain an accurate score. Measure over light clothing.

Total the score on the completed AUSDRISK and write the patient details and score on the front page of the Information Sheet.

Return the completed AUSDRISK brochure to the patient

Ask all patients to sign the Consent Form (on back of Information Sheet) if they agree to their data (de-identified) being provided to the University of Tasmania.

Note on the Information Sheet if they DO NOT AGREE to releasing data.

Read out the recommendations on the AUSDRISK for the risk range that the new patient has scored – irrespective of whether the client agrees to their data being used or not.

If the patient has scored in the High Risk range, state:

Your AUSDRISK score indicates that you have some risk factors for developing Type 2 diabetes. It is not a diagnosis of diabetes.

You are advised to see your doctor and have a medical assessment to determine if you have undiagnosed type 2 diabetes or not. Take your AUSDRISK form with you.

The University of Tasmania is interested in conducting a follow-up telephone interview or short email survey, approximately 6 weeks after completing the AUSDRISK for those people who have scored in the High Risk range, to see if they have been diagnosed with type 2 diabetes or not.

Participation in the follow-up 5 – 10 minute telephone interview or email survey is voluntary. Signing the Consent Form only indicates the patient is willing to have their AUSDRISK results (de-identified) made available to UTAS.

Ask the patient to indicate whether they AGREE or NOT AGREE to being contacted for the 6 week follow-up telephone interview or short email survey.

If the patient agrees to be contacted for follow-up email/phone call, please ensure they have circled AGREE and that their name and contact details are correct on the form and that they have signed the Consent Form. Their responses in the follow-up interview/email will still remain de-identified.

Please thank the patient for participating in the follow-up part of the study.

For all patients irrespective of their AUSDRISK score:

The patient will return the yellow Information Sheets/Consent Forms and the clipboard to the Front Desk. The Front Desk staff will store the completed forms in a folder in a secure locked cupboard in the Team Leader's office. Documentation will be collected every week by the researcher.

All patients retain their AUSDRISK form.

It is up to the Health Professional's professional judgement as to whether the discussion about scoring in the High Risk range and participation in the follow-up study is done at the commencement or at the end of the patient consultation.

For further information or enquiries please contact the UTAS researcher Liz Bingham PH: (03) 62.. .... or mobile 04.. ... .

Implementation of AUSDRISK assessment tool at Clarence Integrated Care Centre

Role of Front of House Service staff.

Introduce the AUSDRISK to new adult clients (18 years and over):

State: Clarence Integrated Care Centre is introducing a type 2 diabetes risk assessment for all new adult clients. It's called the AUSDRISK. It will take you a short time (2-5 minutes) to complete.

First I just want to check:

Question 1. Have you been diagnosed with any form of diabetes?

–if YES, ask –what type? Type 1, Type2, Gestational Diabetes (GDM during pregnancy only)

If yes, to Type 1 or Type 2 – circle which type on the Information Sheet and do not proceed with AUSDRISK; ask approximately how long since you were diagnosed (by a doctor) with Type 1 or Type 2 diabetes – write the approximate date of diagnosis on the Information Sheet.

Please store these sheets securely in the envelope provided.

If NO – to diagnosed with diabetes, or yes to GDM but only during pregnancy – it is suitable for the patient to complete the AUSDRISK.

Proceed with the AUSDRISK assessment:

Hand the clipboard with the AUSDRISK 'package' to the new patient and ask them to read the Information Sheet, and complete the AUSDRISK assessment tool and take the completed papers with them to their appointment with the Therapist or Nurse.

If they are disinclined to complete the form immediately e.g : If they say "will do it later" or "forgotten my glasses" – say it's important to do it now before you start your appointment.

Question 2. Would you like some assistance?— Offer to read out the questions and fill out the form. If you, or another adult, assist the patient, please circle **YES** to the question "Did you need assistance?" on the Information Sheet, BEFORE the patient takes the form to their therapist/nurse

If the patient still does not want to complete the AUSDRISK, do not persist. Write **DECLINED (and the date)** at the top of the Information Sheet. Store securely in the container provided for the diabetes diagnosed sheets.

FREQUENTLY ASKED QUESTIONS

Why do you have to give consent?

- The University of Tasmania needs to know you have agreed to participate in the study
- Providing your name and signature shows you agree to participate

What does it mean to give consent?

- To allow your results from the yellow form to be made available to UTAS for use in a study
- Your name will not be used in this study

High Risk Survey

- Answer 5-6 questions either by telephone or email
- Survey answers are NOT reported against your name

Implementation of AUSDRISK assessment tool at OPSM/Optomeyes

Role of Front of House Service staff.

Introduce the AUSDRISK to new adult clients (45 years and over) attending for:

- **A full eye examination**

State: The University of Tasmania, School of Medicine is working with OPSM/Optomeyes to help Tasmanians to find out if they have type 2 diabetes. This condition has very few symptoms or warning signs. It is important to know your diabetes risk.

OPSM/Optomeyes is introducing this type 2 diabetes risk assessment for all adult clients 45 years and over having a full eye examination. It's called the AUSDRISK. It will take you a short time (2-5 minutes) to complete.

The AUSDRISK identifies if you are at risk of developing type 2 diabetes.

AUSDRISK is not a diagnostic test but it can indicate whether you would benefit from being assessed for diabetes by a GP/medical practitioner and receiving medical advice.

First I just want to check:

Question 1. Have you been diagnosed with any form of diabetes?

–if YES, ask –what type? Type 1, Type2, Gestational Diabetes (GDM during pregnancy only)

If yes, to Type 1 or Type 2 – circle which type on the Information Sheet and do not proceed with AUSDRISK; ask approximately how long since you were diagnosed (by a doctor) with Type 1 or Type 2 diabetes – write the approximate date of diagnosis on the Information Sheet.

If NO – to diagnosed with diabetes, or yes to GDM but only during pregnancy – it is suitable for the patient to complete the AUSDRISK.

Proceed with the AUSDRISK assessment:

Hand the clipboard with the AUSDRISK 'package' to the client and ask them to read the Information Sheet, and complete the AUSDRISK assessment tool and take the completed papers with them to their appointment with the Optometrist.

FREQUENTLY ASKED QUESTIONS

Why do you have to give consent?

- The University of Tasmania needs to know you have agreed to participate in the study
- Providing your name and signature shows you agree to participate

What does it mean to give consent?

- To allow your results from the yellow form to be made available to UTAS for use in a study
- Your name will not be used in this study

High Risk Survey

- Answer 5-6 questions either by telephone or email
- Survey answers are NOT reported against your name

AUSDRISK SURVEY

Are you at risk of developing type 2 diabetes?

The University of Tasmania, School of Medicine is working to help Tasmanians to find out if they have type 2 diabetes. This condition has very few symptoms or warning signs. It is important to know your diabetes risk.

OPSM is working with UTAS School of Medicine to trial the AUSDRISK Assessment Tool (AUSDRISK).

The AUSDRISK identifies if you are at risk of developing type 2 diabetes.

AUSDRISK is not a diagnostic test but it can indicate whether you would benefit from being assessed for diabetes by a GP/medical practitioner and receiving medical advice.

Participation is voluntary. Please read the Consent Form on the back of this Information sheet.

If you have already been medically diagnosed with type 1 diabetes or type 2 diabetes

- **DO NOT complete the AUSDRISK.**
- **Place a tick to indicate which diabetes diagnosis you have and approximate date of diagnosis, and return this form to your optometrist:**

Type 1 diabetes .....year diagnosed..... **Type 2 diabetes** .....year diagnosed .....

INSTRUCTIONS TO COMPLETE THE AUSDRISK:

- You may obtain help from an adult family member, friend or your optometrist to complete the AUSDRISK.
- Answer ALL the AUSDRISK questions
- Measure your waist and record your measurement (in cms) on the AUSDRISK
- Tick the small box to indicate the range for your waist measurement
- ADD UP all the points (in the small boxes ticked)
- Write your final score in the last large box on the AUSDRISK form.
- **People who score in the High Risk range are advised to see their GP/medical practitioner to be assessed for diabetes.**
- **KEEP YOUR COMPLETED AUSDRISK FORM and note the ADVICE provided for your AUSDRISK score**

Are you willing to assist UTAS with this trial? Please write your results in the box below.

Print and sign your name on the Consent Form (over page)

Write your final AUSDRISK score here .....

Your gender (circle whichever is correct) **FEMALE** **MALE**

Your Age .....**years**

Has either of your parents, brothers or sisters been diagnosed with type 1 or type 2 diabetes? Please circle whichever is correct : **YES** **NO**

Did you need assistance to complete AUSDRISK? **YES** **NO**

CONSENT FORM (for all participants)

1. I have understood the instructions and completed the AUSDRISK and written my details requested on page 1 of the 'Information Sheet'.
2. I consent to my AUSDRISK score and details (gender, age, family history of diabetes) on this sheet can be made available to the University of Tasmania, School of Medicine
3. I understand the AUSDRISK is not a diagnostic test and that if I score in the High Risk range I will be advised to see a medical practitioner for a medical assessment. Scoring at High Risk does not mean I have diabetes.
4. I understand that if I score in the High Risk range I will be invited to participate in the follow-up study. This will involve volunteering a very short amount of my valuable time for either a short telephone interview by a UTAS researcher or completing a short email survey.
5. I understand that participating in the follow up component of this study is voluntary.
6. I understand that all my data and details will be securely stored on the University of Tasmania premises for seven years, and will then be destroyed.
7. I agree that research data gathered from me for the study may be published, provided that I cannot be identified as a participant.
8. I understand I may withdraw at any time without any effect, and I may request that any data I have supplied to date be withdrawn from the research.
9. **If you agree to have your answers made available to the UTAS, School of Medicine, please sign this Consent Form, check you have completed the AUSDRISK and filled out the details on the front page.**

Return this Information sheet completed to your optometrist.

NAME.....

SIGNATURE.....DATE:.....

Thank you for your participation

If you scored in the High Risk range (12 points or more) UTAS, School of Medicine would like to contact you again 5-6 weeks after you completed the AUSDRISK.

Please circle: **AGREE or DO NOT AGREE** to receiving a telephone call or email from a University of Tasmania researcher to participate in a short follow-up telephone interview or completing a short email survey. Participation in the follow-up study is voluntary. If you agree, please provide your preferred way for UTAS to contact you.

Phone number (mobile or landline) .....

Email address: .....

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au

SCHOOL OF MEDICINE

UTAS

UNIVERSITY OF TASMANIA

The Directors
Optomeyes
P.O Box 318
GPO HOBART 7001

3/12/2013

Dear Directors

Re: HOO13490

Title: To develop reliable protocol(s) for the effective use of the AUSDRISK assessment tool as the initial step in screening for the diabetes status in adults in Tasmania.

We are seeking formal permission to conduct a research trial to implement the AUSDRISK assessment tool as part of the initial assessment for new patients aged 45 years and over at three *Optomeyes* Optometry Practices. The proposed commencement date would be February 2014.

The research trial would be coordinated by Liz Bingham as part of her Doctoral thesis conducted within the School of Medicine, University of Tasmania. Her supervisors are Assoc. Prof Kate Macintyre, Assoc. Prof Kelly Shaw and Prof John Burgess.

Liz has had extensive planning discussions with Mr Andrew Hogan, Ms Diane Jones and Ms Karen Hurtado, who are supportive of this research initiative involving optometry practices in the identification of people with or at high risk of developing type 2 diabetes.

As you would be aware, in 2011three *Optomeyes* Optometry Practices participated in a pilot trial Liz Bingham conducted to implement the AUSDRISK assessment tool as the initial step in screening for the diabetes status in adults in Tasmania.

This pilot project was a "proof of concept" trial to determine if implementing the AUSDRISK assessment tool in an optometry practice was acceptable to both clients and health professionals. Results showed that implementation was acceptable to all participants and staff. Of the twenty-four (24) clients assessed at *Optomeyes* Optometry Practices, 11 scored High Risk (46%); 9 scored at Intermediate Risk (38%) and 4 at Low Risk (16%).

As indicated by the AUSDRISK assessment tool protocol, all those who scored High Risk (12 points or more) were advised to see their doctor about having a fasting blood glucose test to determine their diabetes status.

The limitations of the trial were that there was no capacity to take the next steps to investigate the client response and follow-up action, nor the action taken by the general practitioners for those who attended for a biomedical assessment.

This proposed study will follow a cohort of High Risk clients to determine client and GP responses and actions, for those individuals classified as High Risk on the AUSDRISK.

In this extended study the same methodology (as pilot study 2011) will be used to implement the AUSDRISK assessment but additional consent for follow-up will be sought from all clients who score High Risk.

There will be no financial cost to the *Optomeyes* Optometry Practices participating.

As per discussions with Andrew Hogan, Diane Jones and Karen Hurtado, all Optomeyes management and staff will be fully consulted and if required, receive training (see protocols attached). There will be regular meetings with participating staff and managers and regular progress reports will be provided.

Please do not hesitate to contact me or Liz Bingham if you have any enquiries or wish to have further discussion regarding this research.

Sincerely

Assoc Prof Kate Macintyre

School of Medicine

University of Tasmania

Cc Mr Andrew Hogan
Ms Diane Jones
Ms Karen Hurtado

BARCODE
Title First name Surname
Address
Suburb State P/code

Dear Title Surname

I am pleased to provide you with your Seniors Card and I encourage you to make the most of your Card by getting out and about in the community and using it to access business services and participate in a range of recreational and leisure activities.

Your Seniors Card is a lifelong card and does not need to be replaced unless it is lost or damaged. Please sign the back of the Card before using it and remember to show your Card before a transaction as businesses are not obliged to honour discounts after a transaction has been completed.

Seniors Card Business Partners generously provide discounts voluntarily and are not reimbursed. I encourage you to support these businesses by looking for the Seniors Card logo when you shop for goods and services to ensure the ongoing success of the Seniors Card Program. Details of discounts available are contained in the Seniors Card Directory. You can keep up to date with new or amended offers by visiting the Seniors Card website at www.seniors.tas.gov.au

If you need to update your Seniors Card contact details or would like to replace a lost or damaged Card, please call 1300 13 55 13 or visit any of the 27 Service Tasmania shops around the State.

You will also find enclosed an AUSDRISK Diabetes Risk Assessment Tool (red brochure), an AUSDRISK Survey (yellow A4) and a reply paid envelope. I encourage you to complete the red brochure and if necessary, take it to your doctor to discuss. I also encourage you to consider completing the yellow brochure survey and returning it in the reply paid envelope. Printing your name on this survey form only gives University of Tasmania consent to use your scores; at no time will your name be published or used in this study. To help with the survey's statistics please return the yellow brochure in the reply paid envelope even if you do not wish to complete the survey.

As a valued member of the Tasmanian community I hope you enjoy the benefits of your Seniors Card and I encourage you to take advantage of the many opportunities it provides.

Yours sincerely

Alex Schouten (Ms)
Manager Programs and Services

AUSDRISK SURVEY

Are you at risk of developing type 2 diabetes?

The University of Tasmania, School of Medicine (UTAS) is working to help adult Tasmanians find out if they are at risk of developing type 2 diabetes. This condition has very few symptoms or warning signs. It is important to know your diabetes risk, as there are ways of reducing your risk of diabetes and its complications.

Seniors' Card is working with UTAS to distribute the AUSDRISK Assessment Tool (AUSDRISK).

The AUSDRISK identifies if you are at risk of developing type 2 diabetes.

The AUSDRISK Assessment Tool is **not a diagnostic test** but it can indicate whether you would benefit from being assessed for diabetes by a GP/medical practitioner and receiving medical advice.

Participation is voluntary. Please read the Consent Form on the back of this Information sheet. If you do not wish to participate, do not complete this form but please return it in the Reply Paid envelope.

If you have been medically diagnosed with type 2 diabetes, or type 1 diabetes, DO NOT complete AUSDRISK.

Place a tick to indicate which diabetes diagnosis you have, and approximate date of diagnosis, and return this form in the Reply Paid envelope:

Type 2 diabetes .....year diagnosed.....; **Type 1 diabetes .....year diagnosed .....**

INSTRUCTIONS TO COMPLETE THE AUSDRISK:

- You may obtain help from an adult family member or friend to complete the AUSDRISK.
- Answer ALL the AUSDRISK questions
- Measure your waist and record your measurement (in cms) on the AUSDRISK
- Tick the small box to indicate the range for your waist measurement
- ADD UP all the points in the small boxes ticked, and
- Write your final score in the last large box on the AUSDRISK form.
- **People who score in the High Risk range are advised to see their GP/medical practitioner to be assessed for diabetes.**
- **KEEP YOUR COMPLETED AUSDRISK FORM and note the ADVICE provided for your AUSDRISK score**

- **Are you willing to assist UTAS with this trial? Please write your results in the box below.**
- **Print and sign your name on the Consent Form (over page), and return this Information sheet completed in the Reply Paid envelope.**

Write your final AUSDRISK score here .....

Your gender (circle whichever is correct) FEMALE MALE

Your Age .....years

Has either of your parents, brothers or sisters been diagnosed with type 1 or type 2 diabetes? Please circle whichever is correct : YES NO

CONSENT FORM (for all participants in the AUSDRISK survey)

1. I have understood the instructions and completed the AUSDRISK and written my details requested on page 1 of the 'Information Sheet'.
2. I consent to my AUSDRISK score and details (gender, age, family history of diabetes) on this sheet can be made available to the University of Tasmania, School of Medicine
3. I understand the AUSDRISK is not a diagnostic test and that if I score in the High Risk range I will be advised to see a medical practitioner for a medical assessment. Scoring at High Risk does not mean I have diabetes.
4. I understand that if I score in the High Risk range I will be invited to participate in the follow-up study. This will involve volunteering a very short amount of my valuable time for either a short telephone interview by a UTAS researcher or completing a short email survey.
5. I understand that participating in the follow up component of this study is voluntary.
6. I understand that all my data and details will be securely stored on the University of Tasmania premises for seven years, and will then be destroyed.
7. I agree that research data gathered from me for the study may be published, provided that I cannot be identified as a participant.
8. I understand I may withdraw at any time without any effect, and I may request that any data I have supplied to date be withdrawn from the research.
9. **If you agree to have your answers made available to the UTAS School of Medicine, please sign this Consent Form, check you have completed the AUSDRISK and filled out the details on the front page.**
10. **Return this Information sheet completed in the Reply paid envelope.**

NAME.....

SIGNATURE.....DATE:.....

Thank you for your participation

If you scored in the High Risk range (12 points or more) UTAS School of Medicine would like to contact you again 5-6 weeks after you completed the AUSDRISK.

Please circle: **AGREE or DO NOT AGREE** to receiving a telephone call or email from a University of Tasmania researcher to participate in a short follow-up telephone interview or completing a short email survey. Participation in the follow-up study is voluntary. If you agree, please provide your preferred way for UTAS to contact you.

Phone number (mobile or landline) .....

Email address: .....

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au

Appendix 3 page216

AUSDRISK Survey

AUSDRISK Survey

This is a survey to follow up on your initial AUSDRISK assessment.

1. Please enter your contact details so we can identify your response with your name. Your contact details and responses are not made public.

Name

Email Address

Phone Number

2. Have you seen your GP about your AUSDRISK result?

Yes - go to Question 3

No - go to Question 9

3. When you saw your GP did you have blood tests to check if you had diabetes?

Yes - go to Question 4

No - go to Question 8

4. If you had blood tests did the results show you had type 2 diabetes?

Yes - please answer Questions 5 and 6

No - please answer Questions 7 and 8

5. If you were found to have diabetes on your blood tests, did the GP prescribe tablets to manage your diabetes?

Yes

No

6. Did the GP advise changes to your lifestyle

Yes - end of survey

No - end of survey

7. If your blood tests showed no diabetes, did the results show pre-diabetes or high

blood sugar?

Yes

No

Don't know

8. Did the GP discuss lifestyle changes to reduce your risk for developing type 2 diabetes in the future?

Yes - end of survey

No - end of survey

9. Will you go and see your GP about your AUSDRISK result?

Yes

No

Thank you for participating in the diabetes risk assessment study being conducted by the University of Tasmania's School of Medicine. Your time and interest is greatly appreciated.

Done

FW: Seniors Card diabetes risk assessment follow-up survey

Elizabeth Bingham

Dear Seniors' Card recipient

Last year (during the period August-September 2014) when you received your Seniors' Card, you participated in a diabetes risk assessment study being conducted by the University of Tasmania, School of Medicine. You completed the AUSDRISK type 2 diabetes risk assessment brochure and scored in the high risk range.

Thank you for signing a yellow form to indicate you would be willing for the School of Medicine to receive your AUSDRISK diabetes risk assessment score (but not your name) and that a university researcher could contact you at a later date.

This email is in relation to your AUSDRISK diabetes risk assessment. We would appreciate you answering the following 8-9 YES/NO questions in this survey to help us understand the effectiveness of the AUSDRISK.

CLICK ON THIS LINK TO ACCESS THE SURVEY;
https://www.surveymonkey.com/s/3BHX9NR

Thank you for participating in the diabetes risk assessment study being conducted by the University of Tasmania's School of Medicine. Your time and interest is greatly appreciated.

Liz Bingham
Candidate, Doctorate of Health
University of Tasmania School of Medicine
Email: bethuneb@utas.edu.au

Appendix 3: Follow up survey invitation for Direct recruited HR participants

FW: Diabetes Risk Assessment Study

Elizabeth Bingham

Fri 16/01/2015 11:49 AM

Last year when you signed in for an appointment at the front desk of Clarence Integrated Care Centre, you participated in a diabetes risk assessment study being conducted by the University of Tasmania School of Medicine. You completed the AUSDRISK type 2 diabetes risk assessment brochure and scored in the high risk range.

Thank you for signing a yellow form to indicate you were willing for the School of Medicine to receive your AUSDRISK Diabetes Risk assessment score (but not your name) and that a university researcher could contact you at a later date.

This email is in relation to your AUSDRISK Diabetes Risk assessment. We would appreciate you answering the following 8-9 YES/NO questions in this survey to help us understand the effectiveness of the AUSDRISK.

CLICK ON THIS LINK TO ACCESS THE SURVEY: https://www.surveymonkey.com/s/3BHX9NR

Thank you for participating in the diabetes risk assessment study being conducted by the University of Tasmania's School of Medicine. Your time and interest is greatly appreciated.

Liz Bingham
Candidate, Doctorate of Health
University of Tasmania School of Medicine
Email: bethuneb@utas.edu.au

Appendix 3: HR participants' follow up survey p 1

AUSDRISK Survey

AUSDRISK Survey

This is a survey to follow up on your initial AUSDRISK assessment.

1. Please enter your contact details so we can identify your response with your name. Your contact details and responses are not made public.

Name

Email Address

Phone Number

2. Have you seen your GP about your AUSDRISK result?

Yes - go to Question 3

No - go to Question 9

3. When you saw your GP did you have blood tests to check if you had diabetes?

Yes - go to Question 4

No - go to Question 8

4. If you had blood tests did the results show you had type 2 diabetes?

Yes - please answer Questions 5 and 6

No - please answer Questions 7 and 8

5. If you were found to have diabetes on your blood tests, did the GP prescribe tablets to manage your diabetes?

Yes

No

6. Did the GP advise changes to your lifestyle

Yes - end of survey

No - end of survey

7. If your blood tests showed no diabetes, did the results show pre-diabetes or high

Appendix 3: HR participants follow-up survey p 2

blood sugar?

Yes

No

Don't know

8. Did the GP discuss lifestyle changes to reduce your risk for developing type 2 diabetes in the future?

Yes - end of survey

No - end of survey

9. Will you go and see your GP about your AUSDRISK result?

Yes

No

Thank you for participating in the diabetes risk assessment study being conducted by the University of Tasmania's School of Medicine. Your time and interest is greatly appreciated.

Done

Questionnaire by Phone Introduction	Good afternoon/morning. My name is Liz Bingham. I am a researcher at the University of Tasmania School of Medicine. You participated in a Diabetes Survey – the AUSDRISK type 2 diabetes risk assessment tool -about 5-6 week's ago. You scored High Risk on the AUSDRISK. You agreed to answer some questions after the survey.	
Q1 May I check your name?		Site CICC OPTOM Seniors' Card
Q 2 Do you still consent to answer 5-6 questions?	YES Interviewer reiterates the purpose of the follow-up telephone interview: To follow-up people who have scored in the HR range of the AUSDRISK to find out what actions they have taken or had been able to take, in determining their diabetes status Go to Q 3	NO Could you advise why it is no longer convenient? ? no time/no longer interested If not interested, why (gently)
Q 3 Have you been able to see your GP to discuss further assessment as recommended by the AUSDRISK? Y/N	YES - GO to Q4	NO – why unable to see GP so far – Do you plan to see your GP? Y/N If Yes – appointment scheduled? If Y – date? May I contact you after that Date? If N – would you be happy to tell me why you don't plan to see your GP? Go to Q 5
Q 4 If Yes to Q 3	Did you have tests Y/N Yes – Results If No (to tests)-Did the GP give you any other directions Medication? Lifestyle? Tests later?	Q 5 If No to Q 3 NO – Do you plan to see another health/lifestyle professional?
Q 6 May I just re-check the details you provided when you completed the AUSDRISK?	Gender Age Family History of Diabetes	
May I ask how you felt when you scored in the HR range?	Do you have any questions you would like to check with me? Lifestyle modifications Where to seek help	Thank you for participating. The University of Tasmania Medical School really appreciates the time you have given to this research We hope the results of this research will help us promote the importance of knowing your diabetes status and help people manage diabetes well and lead a happy life.

Office of Research Services
University of Tasmania
Private Bag 1
Hobart Tasmania 7001
Telephone + 61 3 6226 7479
Facsimile + 61 3 6226 7148
Email Human.Ethics@utas.edu.au
www.research.utas.edu.au/human_ethics/

HUMAN RESEARCH ETHICS COMMITTEE (TASMANIA) NETWORK

UTAS

18 September 2013

Dr Kate Macintyre
C/- School of Medicine

Sent via email

Dear Dr Macintyre

REF NO: H0013490
TITLE: To develop reliable protocol(s) for the effective use of the AUSDRISK assessment tool as the initial step in screening for diabetes status in adults in Tasmania

Document	***Version***	***Date***
Low Risk Application Form	-	-
AUSTOOL Flyer	-	-
CICC Implementation of AUSDRISK - staff roles & responsibilities	Version 1	19 Aug 2013
Clarence ICC information and consent form 190813 Vers 01	Version 1	19 Aug 2013
Mailout information and consent form	Version 1	19 Aug 2013
Optomeyes information and consent form	Version 1	19 Aug 2013
Optomeyes Implementation of AUSDRISK assessment tool	Version 1	19 Aug 2013
Six week post- AUSDRISK telephone or survey questions	Version 1	19 Aug 2013

The Tasmania Health and Medical Human Research Ethics Committee considered and approved the above documentation on **18 September 2013** to be conducted at the following site(s):

Clarence Integrated Care Centre
Optomeyes® optometry group (3 practices in Southern Tasmania)

Please ensure that all investigators involved with this project have cited the approved versions of the documents listed within this letter and use only these versions in conducting this research project.

This approval constitutes ethical clearance by the Health and Medical HREC. The decision and authority to commence the associated research may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or review by your research governance coordinator or Head of Department. It is your responsibility to find out if the approval of other bodies or authorities are required. It is recommended that the

proposed research should not commence until you have satisfied these requirements.

All committees operating under the Human Research Ethics Committee (Tasmania) Network are registered and required to comply with the *National Statement on the Ethical Conduct in Human Research* (NHMRC 2007 updated 2009).

Therefore, the Chief Investigator's responsibility is to ensure that:

(1) The individual researcher's protocol complies with the HREC approved protocol.

(2) Modifications to the protocol do not proceed until **approval** is obtained in writing from the HREC. Please note that all requests for changes to approved documents must include a version number and date when submitted for review by the HREC.

(3) Section 5.5.3 of the National Statement states:

Researchers have a significant responsibility in monitoring approved research as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies and take prompt steps to deal with any unexpected risks.

The appropriate forms for reporting such events in relation to clinical and non-clinical trials and innovations can be located at the website below. All adverse events must be reported regardless of whether or not the event, in your opinion, is a direct effect of the therapeutic goods being tested.
http://www.research.utas.edu.au/human_ethics/medical_forms.htm

(4) All research participants must be provided with the current Patient Information Sheet and Consent Form, unless otherwise approved by the Committee.

(5) The Committee is notified if any investigators are added to, or cease involvement with, the project.

(6) This study has approval for 4 years contingent upon annual review. A *Progress Report* is to be provided on the anniversary date of your approval. Your first report is due **18 September 2014.** You will be sent a courtesy reminder closer to this due date.

(7) A *Final Report* and a copy of the published material, either in full or abstract, must be provided at the end of the project.

Should you have any queries please do not hesitate to contact me on (03) 6226 2764.

Yours sincerely

Lauren Black
Ethics Officer, Health and Medical Human Research Ethics Committee
Office of Research Services
Tel: +61 (03) 6226 2764
Email: lauren.black@utas.edu.au
University of Tasmania
Private Bag 01 Hobart Tas 7001

Tasmanian Health and Medical Human Research Ethics Committee
Low Risk Application Form

An electronic version of this Low Risk form and attachments must be emailed to Katherine.Shaw@utas.edu.au

A signed hard copy should be mailed to Human Research Ethics, Pte Bag 1, Sandy Bay 7001

If you have any questions please call 6226 7479

1. TITLE OF PROPOSED INVESTIGATION

- To develop reliable protocol(s) for the effective use of the AUSDRISK assessment tool as the initial step in screening for diabetes status in adults in Tasmania.

2. APPLICANTS

The term 'investigator' is used to cover staff and students in their roles as researchers or educators. The 'Chief Investigator' (sometimes referred to as the Principal Investigator') is ultimately responsible for the conduct of the project and should be named first. A student cannot be the Chief Investigator on a project.

All applicants must sign the form (Section C: Declarations)

Chief Investigator/Supervisor:	**Name:** Assoc. Prof. Kate Macintyre
Position:	School of Medicine, University of Tasmania
Phone:	
Email:	Kate.Macintyre@utas.edu.au
Other Investigator:	**Name:** Assoc. Prof. Kelly Shaw
Position:	Senior Clinical Lecturer, School of Medicine, UTAS
Phone:	Work: (03) 62..... Mobile:04.. ... ...
Email:	kelly.shaw@dhhs.tas.gov.au
Other Investigator:	Professor J. R. Burgess

Position:	Professor of Endocrinology, School of Medicine, University of Tasmania
Phone:	
Email:	J.R.Burgess@utas.edu.au

UTas Student Investigator Details (if applicable)

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Elizabeth Bingham	791688	1.10.42	DHlth
Student email address:		Phone: (03) 62..	Mobile: 04.. ... ...

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Student email address:		**Phone:**	**Mobile:**

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Student email address:		**Phone:**	**Mobile:**

3. PURPOSE

What is the main purpose of this project?

Research ☐ Teaching ☐

Research for Thesis √ Quality Assurance/Audit ☐

4. BRIEF OUTLINE OF PROPOSAL

Aims:

1. Conduct a trial to test the feasibility of implementing the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK), to screen for type 2 diabetes in Tasmanian adults aged 18 years and over in public and private primary health care settings, and via a mail-out to randomly selected adults 60 years and over.
2. To determine the effectiveness and potential of each setting/approach for implementing the AUSDRISK as an/the initial step in a national screening program for type 2 diabetes.
3. To follow-up a minimum of 50 adults in each of the primary healthcare settings who scored in the High Risk range on the AUSDRISK and were advised to seek a biomedical assessment to determine their diabetes status.
4. To document the investigation, diagnosis and management of those who scored in the High Risk range.
5. To implement a mail-out of the AUSDRISK to 150 randomly selected adults over the age of 60

years in Southern Tasmania and evaluate the response rate.

6. To investigate the personal and systemic factors which act as facilitators or barriers to utilisation of the AUSDRISK for a national type 2 diabetes screening program and compare these across different settings.

Justification:

BACKGROUND

There is a current worldwide epidemic of type 2 diabetes. This is expected to increase significantly in the coming years due to the ageing population, increasing prevalence of obesity and other adverse lifestyle factors particularly poor nutrition and insufficient physical activity to gain health benefits.

A National Diabetes Strategy and Action Plan has recently been released by Diabetes Australia® in June 2013 to provide a clear framework for a new national strategy for diabetes and a five year action plan. This framework is strongly aligned with the International Diabetes Federation and global priorities for diabetes prevention and management. There are five major goals, the first two of which highlight the need for prevention of diabetes and its complications.

In Australia there are currently over one million adults over the age of 18 years diagnosed with type 2 diabetes and registered on the National Diabetes Services Scheme managed by Diabetes Australia® (and its state-based branches) . However for every three (3) adults diagnosed with type 2 diabetes, it is estimated that there are another two adults with undiagnosed type 2 diabetes, as well as a proportion who would have pre-diabetes, which places them at high risk of developing type 2 diabetes with early cardiovascular complications.

The Australian Diabetes Obesity and Lifestyle Study "AusDiab" was conducted in the year 2000. It was the first national study of the prevalence of diabetes in Australia.

In Tasmania the prevalence of diabetes in people aged 18 – 64 years was found to be 8.7% of population – an estimate at the time of 43,500 people.

As at 31 March 2013 there were 25,125 people with diabetes (all types) registered on the National Diabetes Services Scheme (NDSS) in Tasmania of whom 21,472 were registered with type 2 diabetes.

Diabetes Tasmania® estimates that based on the known prevalence of diabetes in Tasmania, only 60 per cent of those with type 2 diabetes have been diagnosed. Numerically, there could be another 16,000 – 17,000 adults with undiagnosed type 2 diabetes and a further 40,000 at risk of developing diabetes or pre-diabetes.

The major health issue with type 2 diabetes and pre-diabetes is that both conditions carry a high risk of vascular complications. A diagnosis of diabetes/pre-diabetes allows for implementation of medication and lifestyle measures to achieve good control of the metabolic status, and prevent or delay the onset of life-threatening complications.

Type 2 diabetes is bio-medically diagnosed via a series of fasting blood tests which are relatively costly and impractical for whole of population screening.

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)* was developed in 2008 to identify those people with or at high risk of developing type 2 diabetes. Those identified as at high risk are then advised to attend their General Practitioner to have a biomedical assessment (blood tests) to determine their diabetes status

Since its development in 2008, the AUSDRISK has not been widely used in Australia for population screening or to raise people's awareness of their risk of type 2 diabetes. Little is known as to why there has been poor utilisation of the AUSDRISK. A recent study (2011) amongst GPs in NSW found that only 22% were aware

of the AUSDRISK assessment tool.

In Tasmania there is no population health screening for type 2 diabetes. Ad hoc opportunistic screening for type 2 diabetes is performed in general practices when time permits, and "finger prick" screening is performed on occasions such as during annual health promotion initiatives such as the National Diabetes Week and World Diabetes Day.

In February-March 2011, a 6 week pilot "proof of concept" study for implementation of the AUSDRISK was conducted in the Southern Tasmania Health Area.

The aim was to test the acceptability and feasibility for both clients and health professionals of implementing the AUSDRISK in two primary healthcare settings - a Community Health Nursing Service in the public health sector and in two (2) optometry practices in the private health sector. Diabetes screening was not part of routine practice in either setting.

Forty two (42) adult clients voluntarily participated in the study. None was previously diagnosed with diabetes. Seventeen (17) adult clients were assessed in the optometry practices and 25 in the wound care management clinic of a community nursing service. Females represented 80% of the wound care and 100% of the optometry cohorts respectively.

The findings of the trial suggested that implementation of the AUSDRISK in these healthcare settings was acceptable and effective for all participants, and identified people at high risk for type 2 diabetes.

Forty-eight per cent (48%) of those assessed using AUSDRISK, scored in the high risk category. None of those who scored "high risk" had been previously tested for diabetes even if they had a family history of diabetes.

All those identified as high risk stated their intention to follow up with their GP for biomedical assessment.

The limitations were that the trial was designed as a "proof of concept" for the initial step in implementation of the AUSDRISK in primary healthcare settings and as such there was no capacity to take the next steps to investigate the client response and follow-up action, nor the action taken by the general practitioners for those who attended for a biomedical assessment.

So whilst the proof of concept for initial implementation of the AUSDRISK was achieved there are many unanswered questions around the longer term effectiveness of implementing the AUSDRISK in these settings. The next step will be to extend the "proof of concept" implementation of the AUSDRISK by increasing the numbers of adults screened to develop a cohort of 150 who scored in the High Risk range.

This proposed study will follow a cohort of 150 High Risk clients to determine client and GP responses and actions, for those individuals classified as High Risk on the AUSDRISK.

In this extended study the same methodology (as pilot study 2011) will be used to implement the AUSDRISK assessment but additional consent for follow-up will be sought from all clients who score High Risk.

The High Risk clients will be requested to provide contact details and permission to contact them by phone/email some 6 weeks after the AUSDRISK assessment to determine the outcome of their intention to seek biomedical assessment. If they had been seen by a GP (Y/N); if they had received biomedical testing(Y/N); if tested, the results of test (diabetes Y/N or pre-diabetes Y/N); GP recommendations to client and ongoing management.

In addition to extending the previous proof of concept trial, an additional potential source for implementing the AUSDRISK will be investigated.

To date the AUSDRISK has not been used as a scheduled "mail out" to adults to invite their participation *to* self-assess their diabetes risk, in the manner of the current bowel cancer screening initiative which aims to reach all adults at age 55 and again at age 65 years.

In this extended study a mail-out to 150 randomly selected adults aged 60 years or older will be utilised, as one of the potential ways of reaching adults at high risk of type 2 diabetes and responses/non response and

outcomes recorded and evaluated.
Period of investigation: Please give <u>expected</u> commencement and completion dates of the investigation. **Commencement date:** 1.2.2014 **Completion date:** 31.8.2014

5. REVIEW OF ETHICAL CONSIDERATIONS *Research is only considered to be Low Risk if you answer in the negative to all the following questions. If you answer in the positive, you must complete a full application using the NEAF (National Ethics Application Form)*	
Is your research a clinical trial? (A clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedure and devices, a preventative procedure or a diagnostic device or procedure)	No √ Yes ☐
Does your research involve the administration of medication or placebo beyond the normal routine care of the participant (if under medical care)?	No √ Yes ☐
Does your research involve an innovation in clinical practice or complementary medicine? (An innovation is defined as a new diagnostic or therapeutic method that aims to improve health outcomes but which has not yet been fully assessed for safety and/or efficacy. The spectrum of innovations may range widely from minor variations or extensions of existing methods to new indications, through to completely novel technologies)	No √Yes
Does your research involve the collection of human tissue samples beyond the normal routine care of the participant (if under medical care)? Human tissue samples include blood and other bodily fluids.	No √ Yes ☐
Does your research involve the use of gametes and/or human embryos?	No √ Yes ☐
Does your research involve the use of human stem cells?	No √ Yes ☐

Does you research involve genetic testing?	No √ Yes ☐
Does your research involve the deception of participants, including concealing the purposes of research, covert observation and/or audio or visual recording without consent?	No √ Yes ☐
Does your research involve the participation of people without their prior consent?	No √ Yes ☐
Does your research involve withholding from one group specific treatments or methods of learning from which they may benefit?	No √ Yes ☐
Does your research involve the access or use of medical records where participants can be identified or linked to their records in some way?	No √ Yes
Does your research involve the use of ionising radiation?	No √ Yes ☐
Does your research involve the use of personal data obtained from a Commonwealth or State Government Department/Agency without the consent of the participants e.g. getting a list of addresses from the Australian Electoral Commission?	No √ Yes ☐
Does your research **specifically target** any of the following groups of people; (specifically target means they are the central group of participants, as opposed to potentially being incidentally recruited as part of the general population) • Women who are pregnant and the human foetus • Children and young people • Those highly dependent on medical care who are unable to give consent • People with a cognitive impairment, intellectual disability or mental illness • People who may be involved in illegal activities or residents of custodial institutions • Aboriginal and Torres Strait Islander Peoples • People in other countries • People who are unable to give informed consent because of difficulties in understanding an information sheet (i.e. non English speakers etc)	No √ Yes ☐

Does your research pose any risks for participants under medical care beyond those of their routine care? (Risks include not only physical risks but also psychological, spiritual and social harm or distress eg stigmatisation or discrimination)	No √ Yes ☐
Does your research involve the in depth discussion of any of the following topics whether by interview or as part of a questionnaire or survey; • Parenting practices, • Sensitive personal issues, • Sensitive cultural issues, • Grief death or serious traumatic loss, • Depression mood states or anxiety, • Gambling, • Eating disorders, • Illicit drug taking or substance abuse, • Psychological disorders, • Suicide, • Gender identity and/or sexuality, • Race and/or ethnic identity, • Fertility and/or termination of pregnancy	No √ Yes ☐
Does your research involve the potential disclosure of illegal activities or criminal behaviour?	No √ Yes ☐
Are there any specific risks to the researcher (i.e. will the research involve the use of hazardous materials or be undertaken in a politically unstable area)?	No √ Yes ☐
If your research will take place in an overseas setting do any of the following apply: is the research to be undertaken in a politically unstable area? Does it involve sensitive cultural issues? And/or: will the research take place in a country in which criticism of the government and institutions might put participants and/or researchers at risk?	No √ Yes ☐
Does your research explore potentially confidential business practices or seek to elicit potentially confidential commercial information from participants?	No √ Yes ☐
Does your research explore potentially divergent political views or involve the collection of politically sensitive information?	No √ Yes ☐

5. FUNDING

Under the National Statement (2.2.6) a researcher must disclose:

- *the amount and sources or potential sources of funding for the research; and*
- *financial or other relevant declarations of interest of researchers, sponsors or institutions*

Do the investigators have any financial interest in this project? No √ Yes ☐

If this Application relates to a Grant(s) and/or Consultancies, please indicate the title and Number relating to it:

Funding Body:	Amount:
Funding Body:	Amount:

If no external funding has been obtained, please indicate how any costs of research will be met: Costs covered by industry partners through in-kind contribution.

6. RECRUITMENT

Selection of subjects

There will be two (2) recruitment processes for participants in this study/trial

1. The initial selection of adults to complete the AUSDRISK will be from the two primary healthcare services (one in the public health sector, the other in the private health sector) plus those adults aged 60 years and over who receive an AUSDRISK via the mail-out.
2. The second selection will be those subjects from the two primary healthcare sectors and the mail-out who scored in the High Risk range on the AUSDRISK. They will be invited to participate in the follow-up component of the study.

Initial recruitment:

- Mail-out – random selection of 150 adults aged 60 years and over will receive an AUSDRISK assessment form with information regarding the trial and request to complete the AUSDRISK and an invitation to participate in a follow-up if scoring in the High Risk range.
- Private healthcare sector - Clients aged 45 years and over attending for a full eye examination with pupil dilatation at three Optomeyes® group optometry practices in Southern Tasmania will be invited by their treating optometrist to participate. The commencement age for recruitment was recommended by the participating optometrists who advised that the through-put for full eye assessments was low for adults under the age of 45 years, along with the relatively lower type 2 diabetes risk in the younger age groups.
- Public healthcare sector - All new adult patients (adults 18+years) attending for health services conducted at the Clarence Integrated Care Centre (CICC), Bellerive, Tasmania will be invited by the CICC admission staff and their treating health professional to participate. The wider age range chosen for the new patients at Clarence Integrated Care Centre (CICC) is due to the CICC management wishing to trial the process of AUSDRISK implementation as a regular component for

ALL new patient assessments.

There are no gender criteria and the age range chosen is mainly reflective of the 2013 registration of adults with type 2 diabetes, on the National Diabetes Services Scheme (NDSS) database in Tasmania.

As at 31st May 2013 there were 21,728 adults over the age of 20 years with type 2 diabetes 11,527 males and 10,201 females.

As indicated in the figures below there is low prevalence of type 2 diabetes in adults aged less than 40 years. Finding a cohort of 100 people scoring at High Risk on the AUSDRISK is unlikely in the younger ages range.

	21-39 yrs	40-49 yrs	50-59 years	60–69years	70-79years	80-81years	90+years	
Male	225	860	2244	3676	2978	1370	174	11 527
Female	358	983	1812	2777	2500	1456	314	10 201
Total	583	1843	4056	6453	5478	2826	488	21 728
Percentage	2.68%	8.57%	18.67%	29.69%	25.21%	13.0%	2.25%	100%

Recruitment of subjects

Following extensive discussion of the AUSDRISK trial aims and processes between the researcher and the managements of the Clarence Integrated Care Centre and the Optomeyes® optometry practices in southern Tasmania both organisations have agreed to participate in this AUSDRISK trial. Both organisations participated in the initial pilot study of the AUSDRISK implementation in 2011-12.

All health professional staff members will be provided with written protocols to follow for introducing the trial and inviting the clients to participate (see documentation attached).

All participants will be provided with an AUSDRISK 'package' in which is included:

- a Participant Information Sheet;
- a Consent Form to participate in the trial;
- an AUSDRISK assessment form;
- a paper tape measure and instructions on how to measure waist circumference

Optomeyes® clients:

All adult clients aged 45 years and over (not previously diagnosed with diabetes) attending for a full eye examination with pupil dilation at three Optomeyes® optometry practices (private health sector) in Southern Tasmania will receive a personal invitation from their optometrist to participate in the AUSDRISK trial. The optometrists, trained to implement the standardised introduction procedure (see attached Implementation of AUSDRISK Assessment tool at Optomeyes®) will explain the AUSDRISK trial and hand an AUSDRISK package to the client. The client will be invited by the optometrist to read the information sheet; provide consent to participation in the trial by

signing the consent form and to complete the AUSDRISK. Each client will complete the AUSDRISK assessment procedure prior to the dilation drops dilating their pupils (as part of the full eye health assessment) and return the completed form back to the optometrist to check their AUSDRISK score.

Clarence Integrated Care Centre (CICC) new patients:

All New adult Patients (adults 18+years not previously diagnosed with diabetes) attending for health services at the Clarence Integrated Care Centre (CICC), Bellerive, Tasmania will be advised by a Front Desk administration officer trained in AUSDRISK Implementation at CICC, that the CICC is conducting a trial implementation of the AUSDRISK as part of its new patient assessment. All new patients will be invited to complete an AUSDRISK as part of their New Patient admission process. The AUSDRISK 'package' will be handed to them. Each new patient will be invited by the Administration Officer to read the Information Sheet; provide consent to participation in the trial by signing the Consent Form; complete the AUSDRISK and take it with them to their appointment with an Allied Health professional who will check their AUSDRISK score (see attached Implementation protocol).

Mail-Out

Mail-out – An AUSDRISK assessment form with instructions on completion will be mailed out to a random selection of 150 adults aged 60 years and over in Southern Tasmania. Recipients will be invited to participate in an AUSDRISK trial being conducted by the University of Tasmania. Included in the mail-out will be the AUSDRISK 'package' and a Reply Paid pre-addressed envelope.

All mail-out recipients will be requested to return the documentation either completed or not completed to the addressee on the Reply paid envelope.

Information about subjects **Which of the following best describes the identifiability of the data (including tissues) collected?**	
Non-identifiable data (which has never been labelled with individual identifiers, or from which identifiers have been permanently removed, and by means of which no specific individual can be identified)	√
Re-Identifiable (from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets)	
Identifiable (where the identity of a specific individual can reasonable be ascertained. Examples of identifiers include the individuals name, image, date of birth or address).	√☐

If the information is Re-Identifiable or Identifiable, please give details of the information that will be collected. Also indicate how the confidentiality and anonymity of the participants will be protected**:**

Participants who score in the High Risk range and consent to being followed up by telephone interview or email survey will be requested to supply their contact details. All personal information and data will be kept secure – see data storage information p 17.

Analysis and reporting of data from all participants will be de-identifiable.

6. RELEVANT LITERATURE REFERENCES

Please list the most relevant and recent literature references, both by the investigator and/or by others, that support the justification for the study.

AUSDRISK assessment tool:

Chen L, Magliano D, Balkau B, Colagiuri S, Zimmet PZ, Tonkin AM, Mitchell P, Phillips PJ, Shaw JE. AUSDRISK: an Australian Type 2 Diabetes Risk Assessment Tool based on demographic, lifestyle and simple anthropometric measures. Med J Aust. 2010 Mar 1; 192 (4):197-202.

Pasco JA, Kotowicz MA, Henry MJ, Nicholson GC. Evaluating AUSDRISK for predicting incident diabetes in an independent sample of women. Med J Aust. 2010 Sep 20; 193 (6): 374.

Wong KC, Brown AM, Li SC. AUSDRISK – application in general practice. Aust Fam Physician 2011 Jul; 40 (7): 524 – 6.

Comino EJ, Harris MF, Shaw JE, Jayasinghe UW. Detection of type 2 diabetes: what role for associated risk and protective factors and socioeconomic status. Aust Health Rev. 2012 Aug; 36 (3): 349-55.

Davis-Lameloise N, Hernan A, Janus ED, Stewart E, Carter R, Bennett CM, O'Reilly S, Philpot B, Vartiainen E, Dunbar JA. The Melbourne Diabetes Prevention Study (MDPS): study protocol for a randomized controlled trial. Trials 2013, 14:31 http://www.trialsjournal.com/content/14/1/31

Diabetes Screening:

RACGP Guidelines for Diabetes Management in General Practice 2013/14.

National Evidence Based Guideline for Case Detection and Diagnosis of Type 2 Diabetes 2009 (current)

Sargeant LA, Simmons RK, Barling RS, Butler R, Williams KM, Prevost AT, Kinmonth AL, Wareham NJ, and Griffin SJ. Who attends a UK diabetes screening programme? Findings from the ADDITION-Cambridge study. Diabet Med. 2010 September; 27(9): 995–1003.

Klein Woolthuis EP, de Graw WJ, van Gerwen WH, van den Hoogen HJ, van de Lisdonk EH, Metsemakers JF, van Weel C. Screening for type 2 diabetes in primary care using a stepwise protocol: the Diabscreen Study. Primary Care Diabetes. 2007 Dec;1(4): 199-202

Optometry:

Crawford TN, Alfaro DV 3rd, Kerrison JB, Jablon EP. Diabetic retinopathy and angiogenesis. Curr Diabetes Rev. 2009 Feb; 5(1): 8-13.

Curtis TM, Gardiner TA, Stitt AW. Microvascular lesions of diabetic retinopathy: clues toward understanding pathogenesis? Eye (Lond). 2009 Jul; 23 (7): 1496-508. Epub 2009 May 15.

Jackson GR, Barber AJ. Visual dysfunction associated with diabetic retinopathy. Curr Diab Rep. 2010 Oct; 10 (5): 380-4.

Morello CM. Etiology and natural history of diabetic retinopathy: an overview. Am J Health Syst Pharm. 2007 Sep 1; 64 (17 Suppl 12): S3-7.

Howes JH et al. Screening for diabetes in unconventional locations:- Resource implications and economics of screening in optometry practices Health Policy 102 (2011) 193-199

7. PROCEDURES

Adult clients attending practices in two primary healthcare sectors (one in the private health sector and one in the public health sector) will be recruited to complete an AUSDRISK assessment by their treating health professionals (as per *Recruitment of Subjects*).

It is expected that recruitment in the two primary healthcare sectors will continue over a period of six months or until fifty (50) clients/patients scoring in the High Risk category in each of the sectors (total 100 High Risk) have consented to participate in the follow-up component of the study.

The AUSDRISK assessment form will be mailed out to 150 adults over the age of 60 years in the Southern Tasmania region (random selection). The mail-out will be linked to the mail-out of Seniors' Cards. The researcher will have no involvement in this process apart from providing the "AUSDRISK package".

All participants will receive information on the study with instructions on how to complete the AUSDRISK. All participants will be required to provide written consent to participate in the study. See protocols attached.

Those who have scored in the High Risk range on the AUSDRISK will be invited to participate in the follow-up segment of the study. They will have the opportunity to agree or not agree to participate by the choice of providing (or not) their phone or email contact details.

Approximately 6 weeks after completion of the AUSDRISK, a UTAS researcher will conduct a standardised phone interview or send an electronic survey (see interview questions attached) to those clients (from all sectors) scoring in the High Risk range who have given their written consent and provided contact details (phone/email).

The interview schedule template/electronic survey will be available electronically and participant responses will be added during the phone interview or online via email survey. All responses will be held in securely with access only via password on a computer hard drive. Printed copies will be stored in a locked cupboard with access only via a key held by a designated person (UTAS researcher).

Clarence Integrated Care Centre – with new patients as part of their initial assessment,

All front desk administration staff and all Health Professionals at CICC will be trained to implement the AUSDRISK as per protocols attached.

The AUSDRISK trial will be introduced to all New Patients by the front desk admission staff and,if the patient has not previously been diagnosed with diabetes, an AUSDRISK 'package' will be handed to them.

New patients will be invited by the Administration Officer to read the information sheet; provide consent to participation in the trial by signing the consent form; and complete the AUSDRISK.

New patients will complete the AUSDRISK prior to attending their appointment with the Health Professional and take the completed AUSDRISK plus all trial documentation to their appointment.

Health Professionals will check that the AUSDRISK documentation has been completed and write the TOTAL score on the AUSDRISK form and on the front of the Information sheet.

Health professionals will emphasise that the AUSDRISK assessment tool provides an assessment of risk for developing diabetes it is NOT a diagnostic tool. Only a medical practitioner can diagnose diabetes.

- If the AUSDRISK score is less than 12 points, the Health Professional will advise the patient to follow the instructions on the AUSDRISK assessment tool.
- If the AUSDRISK score is 12 points or more, the health professional will discuss the follow-up component of the study for those who score in the High Risk range. The patient will be advised that participation is voluntary and should indicate on the consent form whether they (client)'AGREE' or "DO NOT AGREE" for follow up. If they 'AGREE', they will provide their contact details.
- Health professionals will check that the AUSDRISK total score and the patient's age, gender and family history for Type 2 diabetes are written on the front of the Information sheet.

Health Professionals will place the AUSDRISK trial documentation for each new patient, irrespective of AUSDRISK score and whether patient agrees to further participation, (Information sheet; Consent Form and Information sheet for those patients scoring in the High Risk range) in an envelope; seal it and place it in a sealed container (see Data storage details). The patient will retain their completed AUSDRISK assessment tool either to take to a medical practitioner for a biomedical assessment or for future health assessments.

Optomeyes® - clients having a full eye health assessment

During the first part of the full eye health assessment, the optometrist will check the client's diabetes status and if the client has not been diagnosed with diabetes, the optometrist will introduce the AUSDRISK to the client, and emphasize its relationship to eye health and diabetes.

The optometrist will hand the AUSDRISK 'package' to the client and explain the details and rationale (as per the Optometry Implementation form) and check that the client is willing to participate in the AUSDRISK assessment.

The optometrist will emphasise that the AUSDRISK assessment tool provides an assessment of risk for developing diabetes it is NOT a diagnostic tool. Only a medical practitioner can diagnose diabetes.

The optometrist will advise that after the dilating drops are put in the eyes the client will go to the waiting room and during the time prior to the drops taking effect the client is requested to:

Read the Information Sheet and sign the Consent Form to indicate agreement to participate in the trial and complete the AUSDRISK.

It takes approx. 10 minutes for the pupil to dilate so the client's vision is fine to complete the forms. (This is the advice from the participating optometry group).

- The client will take the completed AUSDRISK and other forms back to the optometrist for the second part of the eye health assessment.
- If the AUSDRISK score is less than 12 points, the client will be advised to follow the instructions on

the AUSDRISK assessment tool.

- If the AUSDRISK score is 12 points or more, the health professional will discuss the follow-up component of the study for those who score in the High Risk range. The client will be advised that participation is voluntary and that they should indicate on the consent form whether they (client)"AGREE" or "DO NOT AGREE" for follow up. If they 'AGREE' they will provide their contact details.
- The optometrist will write the AUSDRISK total score and the patient's age, gender and family history for Type 2 diabetes on the front of the Information sheet.
- The optometrist will place the AUSDRISK trial documentation for ALL CLIENTS (Information sheet; Consent Form and Information sheet for those patients scoring in the High Risk range) in an envelope; seal it and place it in a sealed container (as per Data Storage). The client will keep/retain their completed AUSDRISK assessment tool either to take to a medical practitioner for a biomedical assessment or for future health assessments.
-

Mail-out

An AUSDRISK assessment form with instructions on completion will be mailed out to a random selection of 150 adults aged 60 years and over in Southern Tasmania. The mail-out will be linked to the mail-out of Seniors' Cards. The researcher will have no involvement in this process apart from providing the "AUSDRISK package". Recipients will be invited to participate in an AUSDRISK trial being conducted by the University of Tasmania. Included in the mail-out will be the AUSDRISK 'package' and a Reply Paid pre-addressed envelope. The trial information will include a request to read the Information Sheet and sign the Consent Form to indicate agreement to participate in the study; and instructions to complete the AUSDRISK including the waist circumference measurement; to write the total score on the AUSDRISK brochure and provide details of age, gender and family history on the Information Sheet; and follow the instructions for their score range provided on the AUSDRISK form.- Instructions for those who score High Risk, are to contact their medical practitioner to be considered for a biomedical assessment to determine their diabetes status. Those who score in the High Risk category will have the opportunity to participate in the follow-up telephone interview/electronic survey via email by providing their contact details.

The client will keep/retain their completed AUSDRISK assessment tool to either to take to a medical practitioner for a biomedical assessment or for future health assessments.

All mail-out recipients will be requested to return the documentation (minus the AUSDRISK tool) either completed or not completed to the addressee on the Reply paid envelope.

8. DATA STORAGE

Where will the data be kept?

The data sheets for each client/patient will be placed in individual envelopes and sealed immediately and kept in a locked cupboard in each of the primary healthcare sites during the course of the trial. The UTAS researcher (Liz Bingham) will collect the sealed envelopes each week and on completion of the trial. .

Responses from the primary health care sites and the mail-out will be kept in a locked cupboard at DHHS Population Health where the researcher is employed.

How will the data be kept secure? As above

The data will be kept in locked cupboards with access only via a key held by one designated person at each site and by Liz Bingham at Population Health.

How and when will the data be destroyed?
The data will be shredded 7 years after completion of the project.

Will any personal information be collected from sources other than the subjects themselves (Please refer to Privacy Legislation Section 95A - National Privacy Principles)?
If YES, please declare the sources of the Information i.e. medical records, databases, registries, lists of members from Associations, clubs etc:
No √ Yes ☐ (please detail)

Will data on individual subjects be obtained from any Commonwealth Government agency without seeking the consent of the individuals? *If yes, then please declare which agency and what information is being sought. If you wish to obtain data containing personal information from any Commonwealth Government agency state the names of these agencies, describe the nature of this data and explain the justification for obtaining this information. At the Commonwealth level the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the Privacy Act 1988. The NHMRC requires the HREC to provide information on the cases in which it has approved access to, and use of, data held by Commonwealth Government agencies.*

No √ Yes ☐ (please detail)

11. INFORMATION SHEET

With few exceptions, it is essential that subjects are provided with an information sheet about the study in which they are being asked to participate. The Chair of the HREC will pay close attention to the information that is given.

A copy of the proposed information sheet must be attached to your application form.

Is your proposed Information sheet attached to this application?

Yes √ No ☐ (please provide an explanation as to why)

12. CONSENT FORM

Written evidence of consent is usually required for research involving human subjects. If written consent is to be obtained a copy of the actual consent form that you propose to use. In certain circumstances, the HREC may give approval for consent to be waived (see Chapter 2.3 of the *National Statement*). While written consent is the norm, there are various kinds of studies for which other procedures for obtaining consent are more appropriate (See Chapter 2.2 of *National Statement*).

If you consider that written consent is inappropriate for this project please state your reasons clearly referring to the appropriate sections of the National Statement.

Is a proposed consent form attached to this application?

Yes √ No ☐ (please provide an explanation as to why)

13. APPROVALS FROM OTHER DEPARTMENTS/INSTITUTIONS

Does this project need the approval of any institution other than the University of Tasmania and/or the Department of Health and Human Services (i.e. Department of Education, particular wards in hospitals, prisons, government institutions, or businesses)?

If 'YES', Please indicate below what Institutions are involved and what the status of the Approval.

No √ Yes ☐ (please detail):

Name of Other Institution(s): Status:

Does this project need the approval of any other HREC? If 'YES', Please indicate below which HREC and the status of the application.	No √ Yes ☐ (please detail): Other HREC(s): Status:

14. DECLARATIONS

The Head of School or the Head of Department is required to certify that:

- He or she is familiar with this project and endorses its undertaking;
- The resources required to undertake this project are available;
- The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

If the Head of School/Department is one of the investigators, this statement must be signed by an appropriate person. This will normally be the Head of School/Department in a related area or by the Dean.

Name	
Position	
Signature	
Date	

Conformity with NHMRC Guidelines

The *Chief Investigator* is required to sign the following statement:

I have read and understood the *National Statement on Ethical Conduct in Human Research 2007 and the Australian Code of Conduct for Responsible Research 2007.* I accept that I, as Chief Investigator, am responsible for ensuring that the investigation proposed in this form is conducted fully within the conditions laid down in the *National Statement* and any other conditions specified by the HREC.

Name of chief investigator	Assoc. Prof Kate Macintyre
Signature	
Date	19/08/2013

Signatures of Other Investigators The other investigators should sign to acknowledge their involvement in the project and to accept the role of the Chief Investigator. – N/A		
(Name) Assoc. Prof Kelly Shaw	(Signature)	(Date) 19/08/2013
(Name) Professor J R Burgess	(Signature)	(Date) 19/08/2013
(Name) Liz Bingham	(Signature)	(Date) 19/08/2013

CHECKLIST	
Please ensure that the following documents are included with your application:	
Information sheet/s (if not attached ensure you have explained why in Section 11)	√
Consent form/s (if not attached ensure you have explained why in Section 12)	√
Questionnaires (if applicable)	√
Interview schedules (if applicable)	√
A copy of any permissions obtained i.e. Department of Education, Other HREC, Other Institutions (if applicable)	N/A
All documents relevant to the study, including all information provided to subjects.	√
Telephone Preambles (if applicable)	√
Recruitment Advertisements (if applicable)	N/A
Email Contents (if applicable)	N/A
Has the 'Statement of Scientific Merit' been signed?	√
Have all investigators signed the form?	√

*

Australian Government
Department of Health and Ageing

What is type 2 diabetes?

Type 2 diabetes is a chronic (long-term) disease marked by high levels of sugar in the blood. It occurs when the body does not produce enough insulin (a hormone released by the pancreas) or respond well enough to insulin. Type 2 diabetes is the most common form of diabetes. There are approximately 1 million people with type 2 diabetes currently. This figure is expected to increase significantly in the coming years.

People with diabetes have a higher risk of developing heart disease, stroke, high blood pressure, circulation problems, lower limb amputations, nerve damage and damage to the kidneys and eyes.

Risk factors

Many Australians, particularly those over 40, are at risk of developing type 2 diabetes through lifestyle factors such as physical inactivity and poor nutrition. Family history of diabetes and genetics also play a role in type 2 diabetes.

What can you do to lower your risk of developing type 2 diabetes?

Your lifestyle choices can prevent or, at least, delay the onset of type 2 diabetes.

You cannot change risk factors like age and your genetic background. You ***can*** do something about being overweight, your waist measurement, how active you are, eating habits, or smoking.

If there is type 2 diabetes in your family, you should be careful not to put on weight. Reducing your waist measurement reduces your risk of type 2 diabetes.

By increasing your physical activity and improving your eating habits you can lower your risk. Eat plenty of vegetables and high fibre cereal products every day and use a small amount of fats and oils. Monounsaturated oils, such as olive or canola oil, are the best choice.

You can have type 2 diabetes and not know it because there may be no obvious symptoms.

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

How do you score?

The Australian Type 2 Diabetes Risk Assessment Tool was developed by the Baker IDI Heart and Diabetes Institute on behalf of the Australian, State and Territory Governments as part of the COAG initiative to reduce the risk of type 2 diabetes

Current from: May 2010

6811 (10/07)

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

1. Your age group

Under 35 years	☐	0 points
35 – 44 years	☐	2 points
45 – 54 years	☐	4 points
55 – 64 years	☐	6 points
65 years or over	☐	8 points

2. Your gender

Female	☐	0 points
Male	☐	3 points

3. Your ethnicity/country of birth:

3a. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?

No	☐	0 points
Yes	☐	2 points

3b. Where were you born?

Australia	☐	0 points
Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe	☐	2 points
Other	☐	0 points

4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)?

No	☐	0 points
Yes	☐	3 points

5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness, during pregnancy)?

No	☐	0 points
Yes	☐	6 points

6. Are you currently taking medication for high blood pressure?

No	☐	0 points
Yes	☐	2 points

7. Do you currently smoke cigarettes or any other tobacco products on a daily basis?

No	☐	0 points
Yes	☐	2 points

8. How often do you eat vegetables or fruit?

Every day	☐	0 points
Not every day	☐	1 point

9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?

Yes	☐	0 points
No	☐	2 points

10. Your waist measurement taken below the ribs (usually at the level of the navel, and while standing)

Waist measurement (cm) ☐

For those of Asian or Aboriginal or Torres Strait Islander descent:

Men	Women		
Less than 90 cm	Less than 80 cm	☐	0 points
90 – 100 cm	80 – 90 cm	☐	4 points
More than 100 cm	More than 90 cm	☐	7 points

For all others:

Men	Women		
Less than 102 cm	Less than 88 cm	☐	0 points
102 – 110 cm	88 – 100 cm	☐	4 points
More than 110 cm	More than 100 cm	☐	7 points

Add up your points ☐

Your risk of developing type 2 diabetes within 5 years*:

☐ *5 or less: Low risk*
Approximately one person in every 100 will develop diabetes.

☐ *6-11: Intermediate risk*
For scores of 6-8, approximately one person in every 50 will develop diabetes. For scores of 9-11, approximately one person in every 30 will develop diabetes.

☐ *12 or more: High risk*
For scores of 12-15, approximately one person in every 14 will develop diabetes. For scores of 16-19, approximately one person in every 7 will develop diabetes. For scores of 20 and above, approximately one person in every 3 will develop diabetes.

**The overall score may overestimate the risk of diabetes in those aged less than 25 years.*

If you scored 6-11 points in the AUSDRISK you may be at increased risk of type 2 diabetes. Discuss your score and your individual risk with your doctor. Improving your lifestyle may help reduce your risk of developing type 2 diabetes.

If you scored 12 points or more in the AUSDRISK you may have undiagnosed type 2 diabetes or be at high risk of developing the disease. See your doctor about having a fasting blood glucose test. Act now to prevent type 2 diabetes.

Implementation of AUSDRISK Assessment Tool at the Clarence Integrated Care Centre for all new adult clients.

Role of Front of House Service Staff

Introduce AUSDRISK to new adult clients

Clarence Integrated Care Centre is introducing a type 2 diabetes risk assessment for all new adult clients. It's called the AUSDRISK. It will take you a short time (2-5 minutes) to complete.

First I just want to check:

Question 1. Have you been diagnosed with any form of diabetes?

–if yes, ask - type 1, type2, Gestational Diabetes (GDM during pregnancy only)

If yes, to type 1 or type 2 – note on Information Sheet and do not proceed with AUSDRISK; ask approximately when were you diagnosed (by a doctor) with type 1 or type 2 diabetes – note approximate date on the Information Sheet.

If yes to GDM, only during pregnancy – suitable to complete the AUSDRISK (follow instructions as for No to diagnosed diabetes).

If NO – to diagnosed with diabetes – hand the AUSDRISK 'package' to the new patient and ask them to read the Information Sheet, and complete the AUSDRISK assessment tool and take the papers with them to their appointment with the Health Professional. If they are disinclined to complete the form immediately e.g : If they say "will do it later" or "forgotten my glasses" – say it's important to do it now before you start your appointment.

Question 2. Would you like some assistance?— offer the front of house staff or suggest that an adult accompanying the client could read out the questions and assist in filling out the form. If they still indicate they do not want to complete the AUSDRISK, do not persist. Note they have DECLINED on the Information Sheet.

Implementation of AUSDRISK Assessment Tool at the Clarence Integrated Care Centre for all new adult clients

Role of Health Professional staff

Ask for the AUSDRISK documentation and thank the patient for completing it – or assist the patient if they have been unable to complete it.

State that the Clarence Integrated Care Centre is conducting a trial for the AUSDRISK to be part of every new patient assessment. As this is a new initiative for CICC, the University of Tasmania (UTAS) is assisting to monitor and evaluate the introduction of the AUSDRISK.

State that the AUSDRISK provides an assessment of the patient's risk for developing type 2 diabetes. It is NOT used to diagnose type 2 diabetes that can only be done by a medical practitioner.

Check that all the AUSDRISK questions have been answered.

If not, offer assistance to complete the AUSDRISK

Check that the patient's waist has been measured.
If not, please use the tape measure (supplied) and ask the patient if you may take a waist measurement in order to obtain an accurate score.

Total the score on the completed AUSDRISK and complete the patient details on the front page of the Information Sheet.

Return the completed AUSDRISK form to the patient

Ask all patients to sign the Consent Form if they agree to their data (de-identified) being provided to the University of Tasmania.

Note on the Information Sheet if they DO NOT AGREE to releasing data.

Read out the recommendations on the AUSDRISK for the risk range that the new patient has scored – irrespective of whether the client agrees to their data being used or not.

If the patient has scored in the High Risk range, refer to:

INFORMATION FOR PEOPLE WHO HAVE SCORED IN THE HIGH RISK RANGE
on the Information Sheet.

'The AUSDRISK score indicates that you have some risk factors for developing Type 2 diabetes. It is not a diagnosis of diabetes.
You are advised to see your doctor and have a medical assessment to determine if you have undiagnosed type 2 diabetes or not.'

The University of Tasmania is interested in conducting a follow-up telephone interview or short email survey, approximately 6 weeks after completing the AUSDRISK for those people who have scored in the High Risk range, to see if they have been diagnosed with type 2 diabetes or not.

Participation in the follow-up 5 – 10 minute telephone interview or email survey is voluntary.

Ask the patient to indicate whether they AGREE or NOT AGREE to being contacted for the 6 week follow-up telephone interview or short email survey.

If the patient agrees to follow-up, please ensure they have circled AGREE and that their name and contact details are correct on the form and that they have signed the Consent Form.

Place all the AUSDRISK documentation (except the AUSDRISK form which the patient retains) in the envelope provided; seal the envelope and place it in a sealed container to be kept in a secure locked cupboard. Documentation will be collected every week by the researcher.

It is up to the Health Professional's professional judgement as to whether the discussion about scoring in the High Risk range and participation in the follow-up study is done at the commencement or at the end of the patient consultation.

For further information or enquiries please contact the UTAS researcher
Liz Bingham PH: (03) 62.. .....

Type 2 diabetes screening at Clarence Integrated Care Centre

Participant Information Sheet on the AUSDRISK assessment tool

Clarence Integrated Care Centre (Clarence ICC) is **introducing the AUSDRISK assessment tool as part of the assessment for all new adult clients attending the CICC.** The aim is to identify adults at risk for developing Type 2 diabetes and assist them to manage their health risk**.**
As this is a new initiative for the Clarence ICC, the University of Tasmania, School of Medicine (UTAS) is assisting to collect data, monitor and evaluate the introduction of the AUSDRISK.

Type 2 diabetes is a health condition which has very few symptoms or warning signs to alert a person that they might be at risk. It is important for people to know their diabetes risk so that the risk can be managed and type 2 diabetes can be prevented/delayed.

The AUSDRISK assessment tool (AUSDRISK) identifies if you are at risk of developing type 2 diabetes. It is **not a diagnostic test** but it can indicate whether you would benefit from having medical tests to confirm whether you have diabetes or not.

DIRECTIONS TO COMPLETE THE AUSDRISK:

- You may gain assistance from a family member or a friend to complete the AUSDRISK.
- Answer ALL the AUSDRISK questions.
- Make sure you measure your waist (in cms) according to the instruction sheet, with the tape measure supplied.
- Write your waist measurement (in cms) in the box and
- Tick the small box that indicates the range for your waist measurement.
- ADD UP all the points (in the small boxes ticked).
- WRITE your final score in the last large box on the AUSDRISK form.
- Keep your completed AUSDRISK form.

ALL Participants are requested to write the following AUSDRISK details on this page

YOUR AUSDRISK SCORE ☐

Your gender (please circle whichever is correct): **Male** **Female**

Your age ……..years.

Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type1 or type 2)**?** Please circle whichever is correct. **NO** **YES**

Please read the Consent Form (on the back of this page).

Print and sign your name if you agree that your AUSDRISK score and details (gender, age, family history of diabetes) can be made available to the University of Tasmania, School of Medicine.

CONSENT FORM (for all participants)

1. I have understood the instructions and completed the AUSDRISK and written the details requested on page 1 of the 'Information Sheet'.
2. I consent to my AUSDRISK score and details (gender, age-range, family history of diabetes) on this sheet can be made available to the University of Tasmania, School of Medicine
3. I understand the AUSDRISK is not a diagnostic test and that if I score in the High Risk range I will be advised to see a medical practitioner for a medical assessment.
4. I understand that if I scored in the High Risk range I will be invited to participate in the follow-up study. This will involve volunteering a very short amount of my valuable time for a telephone interview by a UTAS researcher or completing a short email survey.
5. I understand that participating in the follow up component of this study is voluntary.
6. I understand that all my data and details will be securely stored on the University of Tasmania premises for seven years, and will then be destroyed.
7. I agree that research data gathered from me for the study may be published, provided that I cannot be identified as a participant.
8. I understand I may withdraw at any time without any effect, and I may request that any data I have supplied to date be withdrawn from the research.

Name of Participant:

Signature: _____

Date: _____

If you agree to have your answers made available to the University of Tasmania, School of Medicine, please sign the Consent Form and complete the AUSDRISK and fill out the details on the front page.

If you have NOT scored in the High Risk range you have finished the AUSDRISK research.

Thank you for your participation

If you have scored in the High Risk range on the AUSDRISK, please continue on the next page.

FOR PEOPLE WHO HAVE SCORED IN THE HIGH RISK RANGE

- You are advised to see a medical practitioner to discuss your AUSDRISK score and find out whether further assessment is recommended.
- Make sure you take your completed AUSDRISK assessment tool with you when you attend an appointment with a GP/medical practitioner.
- Scoring at High Risk (12 or more) on the AUSDRISK does NOT mean you have type 2 diabetes. It shows you have some risk factors that put you at higher risk for developing type 2 diabetes.
- *The University of Tasmania, School of Medicine would like to conduct a short telephone interview with* ***those people who score in the High Risk range****, to find out if they had been able to see their GP or medical practitioner about their AUSDRISK result, and whether they were diagnosed with type 2 diabetes or not.*
- *The 5 - 10 minute telephone interview at a time convenient for you, would be conducted by a UTAS researcher, approximately 6 weeks after you have completed the AUSDRISK. Alternatively an email survey would be available.*
  Information that is gathered during the interview or survey will not identify you.
- *It is important that you understand that although you have scored in the High Risk range, your* ***participation*** *in this follow-up part of the study is* ***voluntary.*** *Whilst we would be pleased to have you participate, we respect your right to decline.*

Please circle: **AGREE or DO NOT AGREE** to receiving a telephone call or email from a University of Tasmania researcher to participate in a short follow-up telephone interview or completing a short email survey.

Please provide you contact details if you agree to participate in a telephone interview or email survey.

Contact details (Name and Phone Number or Email address):

.....

Thank you for your participation.

If you have any queries, please contact UTAS researcher Liz Bingham (03) 62.. .....
Please return ALL the pages in the Reply Paid envelope as soon as possible.

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au

Type 2 diabetes screening

Participant Information Sheet on the AUSDRISK assessment tool

The University of Tasmania, School of Medicine (UTAS) is conducting research to determine an effective way of screening for Type 2 diabetes – that is to identify people at risk who don't know it.

This study is NOT for people who have already been diagnosed with Type 1 or Type 2 diabetes, If you have already been diagnosed, please write on the top of this page "DIAGNOSED WITH DIABETES" and return all the papers (uncompleted) in the Reply Paid envelope.

Type 2 diabetes is a health condition which has very few symptoms or warning signs to alert a person that they might be at risk. It is important for people to know their diabetes risk so that the risk can be managed and type 2 diabetes can be prevented/delayed.

The AUSDRISK assessment tool (AUSDRISK) identifies if you are at risk of developing type 2 diabetes. It is **not a diagnostic test** but it can indicate whether you would benefit from having medical tests to confirm whether you have diabetes or not.

DIRECTIONS TO COMPLETE THE AUSDRISK:

- You may gain assistance from a family member or a friend to complete the AUSDRISK.
- Answer ALL the AUSDRISK questions.
- Make sure you measure your waist (in cms) according to the instruction sheet, with the tape measure supplied.
- Write your waist measurement (in cms) in the box and
- Tick the small box that indicates the range for your waist measurement.
- ADD UP all the points (in the small boxes ticked).
- WRITE your final score in the last large box on the AUSDRISK form.
- Keep your completed AUSDRISK form

ALL Participants are requested to write the following AUSDRISK details on this page

YOUR AUSDRISK SCORE ☐

Your gender (please circle whichever is correct): **Male** **Female**

Your age ……. years.

Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type1 or type 2)**?** Please circle whichever is correct. **NO** **YES**

Please read the Consent Form (on the back of this page).

Print and sign your name if you agree that your AUSDRISK score and details (gender, age, family history of diabetes) can be made available to the University of Tasmania, School of Medicine.

CONSENT FORM (for all participants)

1. I have understood the instructions and completed the AUSDRISK and written the details requested on page 1 of the 'Information Sheet'.
2. I consent to my AUSDRISK score and details (gender, age-range, family history of diabetes) on this sheet can be made available to the University of Tasmania, School of Medicine
3. I understand the AUSDRISK is not a diagnostic test and that if I score in the High Risk range I will be advised to see a medical practitioner for a medical assessment.
4. I understand that if I scored in the High Risk range I will be invited to participate in the follow-up study. This will involve volunteering a very short amount of my valuable time for a telephone interview by a UTAS researcher or completing a short email survey.
5. I understand that participating in the follow up component of this study is voluntary.
6. I understand that all my data and details will be securely stored on the University of Tasmania premises for seven years, and will then be destroyed.
7. I agree that research data gathered from me for the study may be published, provided that I cannot be identified as a participant.
8. I understand I may withdraw at any time without any effect, and I may request that any data I have supplied to date be withdrawn from the research.

Name of Participant:

Signature: _____

_____ Date: _____

If you agree to have your answers made available to the University of Tasmania, School of Medicine, please sign the Consent Form and complete the AUSDRISK and fill out the details on the front page.

If you have NOT scored in the High Risk range you have finished the AUSDRISK research.

Thank you for your participation

Please return ALL the pages in the Reply Paid envelope as soon as possible.

If you have scored in the High Risk range on the AUSDRISK, please continue on the next page.

FOR PEOPLE WHO HAVE SCORED IN THE HIGH RISK RANGE

- You are advised to see a medical practitioner to discuss your AUSDRISK score and find out whether further assessment is recommended.
- Make sure you take your completed AUSDRISK assessment tool with you when you attend an appointment with a GP/medical practitioner.
- Scoring at High Risk (12 or more) on the AUSDRISK does NOT mean you have type 2 diabetes. It shows you have some risk factors that put you at higher risk for developing type 2 diabetes.
- *The University of Tasmania, School of Medicine would like to conduct a short telephone interview with* ***those people who score in the High Risk range****, to find out if they had been able to see their GP or medical practitioner about their AUSDRISK result, and whether they were diagnosed with type 2 diabetes or not.*
- *The 5 - 10 minute telephone interview at a time convenient for you, would be conducted by a UTAS researcher, approximately 6 weeks after you have completed the AUSDRISK. Alternatively an email survey would be available.*
  Information that is gathered during the interview or survey will not identify you.
- *It is important that you understand that although you have scored in the High Risk range, your* ***participation*** *in this follow-up part of the study is* ***voluntary.*** *Whilst we would be pleased to have you participate, we respect your right to decline.*

Please circle: **AGREE or DO NOT AGREE** to receiving a telephone call or an email from a University of Tasmania researcher to participate in a short follow-up telephone interview or completing a short email survey.

Please provide you contact details if you agree to participate in a telephone interview or email survey.

Contact details (Name and Phone Number or Email address):

……

Thank you for your participation.

If you have any queries, please contact UTAS researcher Liz Bingham (03) 62.. .....
Please return ALL the pages in the Reply Paid envelope as soon as possible.

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au

Type 2 diabetes screening at Optomeyes®

Participant Information Sheet on the AUSDRISK assessment tool

Optomeyes® is **introducing the AUSDRISK assessment tool as part of the assessment for all adult clients** aged 45 years and over **having a full eye health assessment.** The aim is to identify adults at risk for developing Type 2 diabetes and assist them to manage their eye health risk**.**

As this is a new initiative for Optomeyes®, the University of Tasmania, School of Medicine (UTAS) is assisting to collect data, monitor and evaluate the introduction of the AUSDRISK.

Type 2 diabetes is a health condition which has very few symptoms or warning signs to alert a person that they might be at risk. It is important for people to know their diabetes risk so that the risk can be managed and type 2 diabetes can be prevented/delayed.

The AUSDRISK assessment tool (AUSDRISK) identifies if you are at risk of developing type 2 diabetes. It is **not a diagnostic test** but it can indicate whether you would benefit from having medical tests to confirm whether you have diabetes or not.

DIRECTIONS TO COMPLETE THE AUSDRISK:

- Complete the AUSDRISK in the waiting room while waiting for the dilating eye drops to take effect.
- You may gain assistance from a family member or a friend to complete the AUSDRISK.
- Answer ALL the AUSDRISK questions.
- Make sure you measure your waist (in cms) according to the instruction sheet, with the tape measure supplied.
- Write your waist measurement (in cms) in the box and
- Tick the small box that indicates the range for your waist measurement.
- ADD UP all the points (in the small boxes ticked).
- WRITE your final score in the last large box on the AUSDRISK form.
- **Keep your completed AUSDRISK form.**

ALL Participants are requested to write the following AUSDRISK details on this page

YOUR AUSDRISK SCORE ☐

Your gender (please circle whichever is correct): **Male** **Female**

Your age ……. years

Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type1 or type 2)**?** Please circle whichever is correct. **NO** **YES**

Please read the Consent Form (on the back of this page).

Print and sign your name if you agree that your AUSDRISK score and details (gender, age, family history of diabetes) can be made available to the University of Tasmania, School of Medicine.

CONSENT FORM (for all participants)

1. I have understood the instructions and completed the AUSDRISK and written the details requested on page 1 of the 'Information Sheet'.
2. I consent to my AUSDRISK score and details (gender, age, family history of diabetes) on this sheet can be made available to the University of Tasmania, School of Medicine
3. I understand the AUSDRISK is not a diagnostic test and that if I score in the High Risk range I will be advised to see a medical practitioner for a medical assessment.
4. I understand that if I score in the High Risk range I will be invited to participate in the follow-up study. This will involve volunteering a very short amount of my valuable time for a telephone interview by a UTAS researcher or completing a short email survey.
5. I understand that participating in the follow up component of this study is voluntary.
6. I understand that all my data and details will be securely stored on the University of Tasmania premises for seven years, and will then be destroyed.
7. I agree that research data gathered from me for the study may be published, provided that I cannot be identified as a participant.
8. I understand I may withdraw at any time without any effect, and I may request that any data I have supplied to date be withdrawn from the research.

Name of Participant:

Signature: _____

_____ Date: _____

If you agree to have your answers made available to the University of Tasmania, School of Medicine, please sign the Consent Form and complete the AUSDRISK and fill out the details on the front page.

Give this completed Information Sheet to your optometrist.

Keep your completed AUSDRISK form.

If you have NOT scored in the High Risk range, you have finished the AUSDRISK research.

Thank you for your participation

If you have scored in the High Risk range on the AUSDRISK, please continue on the next page.

FOR PEOPLE WHO HAVE SCORED IN THE HIGH RISK RANGE

- You are advised to see a medical practitioner to discuss your AUSDRISK score and find out whether further assessment is recommended.
- Make sure you take your completed AUSDRISK assessment tool with you when you attend an appointment with a GP/medical practitioner.
- Scoring at High Risk (12 or more) on the AUSDRISK does NOT mean you have type 2 diabetes. It shows you have some risk factors that put you at higher risk for developing type 2 diabetes.
- *The University of Tasmania, School of Medicine would like to conduct a short telephone interview with* ***those people who score in the High Risk range****, to find out if they had been able to see their GP or medical practitioner about their AUSDRISK result, and whether they were diagnosed with type 2 diabetes or not.*
- *The 5 - 10 minute telephone interview at a time convenient for you, would be conducted by a UTAS researcher, approximately 6 weeks after you have completed the AUSDRISK. Alternatively an email survey would be available.*
  Information that is gathered during the interview or survey will not identify you.
- *It is important that you understand that although you have scored in the High Risk range, your* ***participation*** *in this follow-up part of the study is* ***voluntary.*** *Whilst we would be pleased to have you participate, we respect your right to decline.*

Please circle: **AGREE or DO NOT AGREE** to receiving a telephone call or email from a University of Tasmania researcher to participate in a short follow-up telephone interview or completing a short email survey.

Please provide you contact details if you agree to participate in a telephone interview or email survey.

Contact details (Name and Phone Number or Email address):

……

Thank you for your participation.

If you have any queries, please contact UTAS researcher Liz Bingham (03) 62.. .....

Please return ALL the pages in the Reply Paid envelope as soon as possible.

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au

IMPLEMENTATION OF AUSDRISK ASSESSMENT TOOL AT OPTOMEYES®

FOR ALL ADULT CLIENTS HAVING A FULL EYE HEALTH ASSESSMENT

ROLE OF OPTOMETRIST

Introduce AUSDRISK to adult clients having a full eye health assessment

Optomeyes® is introducing a type 2 diabetes risk screening assessment for all adult clients having a full eye health assessment which includes dilating the pupil so that the back of the eye can be fully examined. It's called the AUSDRISK. It will only take you a short time (2-5 minutes) to complete and you do it here.

As this is a new initiative for Optomeyes®, the University of Tasmania (UTAS) is assisting to monitor and evaluate the introduction of the AUSDRISK. Would you like to participate? If NO, do not proceed with AUSDRISK and write "DECLINED" on top of the Information Sheet.

If YES - First I just want to check:

Have you been diagnosed with any form of diabetes?

If YES, ask - Type 1, Type 2, or Gestational Diabetes (GDM during pregnancy only)

If **YES** to Type 1 or Type 2 – NOTE this on the Information Sheet. **Do not proceed** with AUSDRISK. Also note approximately when client was diagnosed (by a doctor) with Type 1 or Type 2 diabetes.

If yes to GDM, **only** during pregnancy – it is **suitable to complete** the AUSDRISK, follow the instructions as for 'No' to diagnosed diabetes (see below).

If NO to diagnosed with diabetes, do the following:

- Handout the AUSDRISK 'package' which contains: the AUSDRISK assessment tool and the INFORMATION SHEET which includes the CONSENT FORM; and the instructions for clients who score in the High Risk range.
- Read out the DIRECTIONS TO COMPLETE THE AUSDRISK to the client.
- Answer any queries the client may have by referring to the Information Sheet.
- Advise the client that they will be able to complete the AUSDRISK in the waiting room whilst they are waiting for the pupil dilating drops to take effect (5-10 minutes).

After inserting the pupil dilation drops –

- Request the client return to the waiting room and complete the required paper work in the next five minutes BEFORE the dilation drops take effect. They may gain assistance from an adult person accompanying them or an Optomeyes® staff member if they need help with filling in the forms.

When client returns the completed AUSDRISK and other forms to you:

Check they have answered all the questions and recorded their waist measurement on the AUSDRISK.

If they don't know their waist measurement, please use the tape measure (supplied) – ask if you may measure their waist size and record (cms) on the AUSDRISK.

ADD up the individual scores to give a **TOTAL SCORE.**

Copy the TOTAL SCORE and the patient details (de-identified) – age, gender, family history, onto the front page of the Information Sheet.

Check that the Consent Form has been signed if they agree to their data (de-identified) being provided to the University of Tasmania.

RETURN the completed AUSDRISK form to the client. RETAIN the completed Information Sheet.

Note on the Information Sheet if the client DOES NOT AGREE to the use of their data.

Read out the recommendations on the AUSDRISK for whichever risk range was scored by the client – Do this whether the client agrees to their data being used or not.

If the client has scored in the High Risk range, refer to the INFORMATION FOR PEOPLE WHO HAVE SCORED IN THE HIGH RISK RANGE on the Information Sheet.

Advise the client that the AUSDRISK score indicates that they have some risk factors for developing Type 2 diabetes. ***It is not a diagnosis of diabetes.***

Advise the client to take their completed AUSDRISK form when they consult their doctor and have a medical assessment to determine if they have undiagnosed type 2 diabetes or not.'

The University of Tasmania is interested in conducting a follow-up telephone interview/email survey for those people who have scored in the High Risk range (and have agreed to the use of their de-identified data) to see if they have been diagnosed with type 2 diabetes or not.

Participation in the **follow-up telephone interview/email survey** component is **voluntary**.

Ask the client to indicate whether they AGREE or NOT AGREE to being contacted for the post-AUSDRISK short 5 – 10 minute follow-up telephone interview/email survey (at approx. 6-weeks).

If the client agrees to participate in the follow-up, please ensure they have circled AGREE and that their name and phone/email contact details are correct on the form and that they have signed the Consent Form.

Place all the AUSDRISK documentation (but not the AUSDRISK form which all clients should retain) in the envelope provided; seal the envelope and place it in a sealed container to be kept in a secure locked cupboard. Documentation will be collected every week by the researcher.

It is up to the Optometrist's professional judgement as to whether the discussion about the High Risk score and participation in the follow-up study is done at the time of first handing the paperwork to the client or at the end of the client's consultation.

For further information or enquiries please contact the UTAS researcher: Liz Bingham PH: (03) 62.. .....

Tasmanian Health and Medical Human Research Ethics Committee Low Risk Application Form

An electronic version of this Low Risk form and attachments must be emailed to Katherine.Shaw@utas.edu.au

A signed hard copy should be mailed to Human Research Ethics, Pte Bag 1, Sandy Bay 7001

If you have any questions please call 6226 7479

1. TITLE OF PROPOSED INVESTIGATION

- To develop reliable protocol(s) for the effective use of the AUSDRISK assessment tool as the initial step in screening for diabetes status in adults in Tasmania.

2. APPLICANTS

The term 'investigator' is used to cover staff and students in their roles as researchers or educators. The 'Chief Investigator' (sometimes referred to as the Principal Investigator') is ultimately responsible for the conduct of the project and should be named first. A student cannot be the Chief Investigator on a project.

All applicants must sign the form (Section C: Declarations)

Chief Investigator/Supervisor:	**Name:** Assoc. Prof. Kate Macintyre
Position:	School of Medicine, University of Tasmania
Phone:	
Email:	Kate.Macintyre@utas.edu.au
Other Investigator:	**Name:** Assoc. Prof. Kelly Shaw
Position:	Specialist Medical Advisor, DHHS, Public and Environmental Health Services
Phone:	Work: (03) 62..... Mobile:04.. ... ...

Email:	kelly.shaw@dhhs.tas.gov.au
Other Investigator:	Professor J. R. Burgess
Position:	Professor of Endocrinology, School of Medicine, University of Tasmania
Phone:	
Email:	J.R.Burgess@utas.edu.au

UTas Student Investigator Details (if applicable)

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Elizabeth Bingham	791688	1.10.42	DHlth
Student email address:		Phone: (03) 622..	Mobile: 04.. ... ...

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Student email address:		Phone:	Mobile:

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Student email address:		Phone:	Mobile:

3. PURPOSE

What is the main purpose of this project?

Research ☐ Teaching ☐

Research for Thesis √ Quality Assurance/Audit ☐

4. BRIEF OUTLINE OF PROPOSAL

Aims:

1. Conduct a trial to test the feasibility of implementing the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK), to screen for type 2 diabetes in Tasmanian adults aged 18 years and over in public and private primary health care settings, and via a mail-out to randomly selected adults 60 years and over.
2. To determine the effectiveness and potential of each setting/approach for implementing the AUSDRISK as an/the initial step in a national screening program for type 2 diabetes.
3. To follow-up a minimum of 50 adults in each of the primary healthcare settings who scored in

the High Risk range on the AUSDRISK and were advised to seek a biomedical assessment to determine their diabetes status.

4. To document the investigation, diagnosis and management of those who scored in the High Risk range.
5. To implement a mail-out of the AUSDRISK to 150 randomly selected adults over the age of 60 years in Southern Tasmania and evaluate the response rate.
6. To investigate the personal and systemic factors which act as facilitators or barriers to utilisation of the AUSDRISK for a national type 2 diabetes screening program and compare these across different settings.

Justification:

BACKGROUND

There is a current worldwide epidemic of type 2 diabetes. This is expected to increase significantly in the coming years due to the ageing population, increasing prevalence of obesity and other adverse lifestyle factors particularly poor nutrition and insufficient physical activity to gain health benefits.

A National Diabetes Strategy and Action Plan has recently been released by Diabetes Australia® in June 2013 to provide a clear framework for a new national strategy for diabetes and a five year action plan. This framework is strongly aligned with the International Diabetes Federation and global priorities for diabetes prevention and management. There are five major goals, the first two of which highlight the need for prevention of diabetes and its complications.

In Australia there are currently over one million adults over the age of 18 years diagnosed with type 2 diabetes and registered on the National Diabetes Services Scheme managed by Diabetes Australia® (and its state-based branches) . However for every three (3) adults diagnosed with type 2 diabetes, it is estimated that there are another two adults with undiagnosed type 2 diabetes, as well as a proportion who would have pre-diabetes, which places them at high risk of developing type 2 diabetes with early cardiovascular complications.

The Australian Diabetes Obesity and Lifestyle Study "AusDiab" was conducted in the year 2000. It was the first national study of the prevalence of diabetes in Australia.

In Tasmania the prevalence of diabetes in people aged 18 – 64 years was found to be 8.7% of population – an estimate at the time of 43,500 people.

As at 31 March 2013 there were 25,125 people with diabetes (all types) registered on the National Diabetes Services Scheme (NDSS) in Tasmania of whom 21,472 were registered with type 2 diabetes.

Diabetes Tasmania® estimates that based on the known prevalence of diabetes in Tasmania, only 60 per cent of those with type 2 diabetes have been diagnosed. Numerically, there could be another 16,000 – 17,000 adults with undiagnosed type 2 diabetes and a further 40,000 at risk of developing diabetes or pre-diabetes.

The major health issue with type 2 diabetes and pre-diabetes is that both conditions carry a high risk of vascular complications. A diagnosis of diabetes/pre-diabetes allows for implementation of medication and lifestyle measures to achieve good control of the metabolic status, and prevent or delay the onset of life-threatening complications.

Type 2 diabetes is bio-medically diagnosed via a series of fasting blood tests which are relatively costly and impractical for whole of population screening.

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)* was developed in 2008 to identify those people with or at high risk of developing type 2 diabetes. Those identified as at high risk are then advised to attend their General Practitioner to have a biomedical assessment (blood tests) to determine their diabetes status

Since its development in 2008, the AUSDRISK has not been widely used in Australia for population screening or to raise people's awareness of their risk of type 2 diabetes. Little is known as to why there has been poor utilisation of the AUSDRISK. A recent study (2011) amongst GPs in NSW found that only 22% were aware of the AUSDRISK assessment tool.

In Tasmania there is no population health screening for type 2 diabetes. Ad hoc opportunistic screening for type 2 diabetes is performed in general practices when time permits, and "finger prick" screening is performed on occasions such as during annual health promotion initiatives such as the National Diabetes Week and World Diabetes Day.

In February-March 2011, a 6 week pilot "proof of concept" study for implementation of the AUSDRISK was conducted in the Southern Tasmania Health Area.

The aim was to test the acceptability and feasibility for both clients and health professionals of implementing the AUSDRISK in two primary healthcare settings - a Community Health Nursing Service in the public health sector and in two (2) optometry practices in the private health sector. Diabetes screening was not part of routine practice in either setting.

Forty two (42) adult clients voluntarily participated in the study. None was previously diagnosed with diabetes. Seventeen (17) adult clients were assessed in the optometry practices and 25 in the wound care management clinic of a community nursing service. Females represented 80% of the wound care and 100% of the optometry cohorts respectively.

The findings of the trial suggested that implementation of the AUSDRISK in these healthcare settings was acceptable and effective for all participants, and identified people at high risk for type 2 diabetes.

Forty-eight per cent (48%) of those assessed using AUSDRISK, scored in the high risk category. None of those who scored "high risk" had been previously tested for diabetes even if they had a family history of diabetes.

All those identified as high risk stated their intention to follow up with their GP for biomedical assessment.

The limitations were that the trial was designed as a "proof of concept" for the initial step in implementation of the AUSDRISK in primary healthcare settings and as such there was no capacity to take the next steps to investigate the client response and follow-up action, nor the action taken by the general practitioners for those who attended for a biomedical assessment.

So whilst the proof of concept for initial implementation of the AUSDRISK was achieved there are many unanswered questions around the longer term effectiveness of implementing the AUSDRISK in these settings. The next step will be to extend the "proof of concept" implementation of the AUSDRISK by increasing the numbers of adults screened to develop a cohort of 150 who scored in the High Risk range.

This proposed study will follow a cohort of 150 High Risk clients to determine client and GP responses and actions, for those individuals classified as High Risk on the AUSDRISK.

In this extended study the same methodology (as pilot study 2011) will be used to implement the AUSDRISK assessment but additional consent for follow-up will be sought from all clients who score High Risk.

The High Risk clients will be requested to provide contact details and permission to contact them by phone/email some 6 weeks after the AUSDRISK assessment to determine the outcome of their intention to seek biomedical assessment. If they had been seen by a GP (Y/N); if they had received biomedical

testing(Y/N); if tested, the results of test (diabetes Y/N or pre-diabetes Y/N); GP recommendations to client and ongoing management.

In addition to extending the previous proof of concept trial, an additional potential source for implementing the AUSDRISK will be investigated.

To date the AUSDRISK has not been used as a scheduled "mail out" to adults to invite their participation to self-assess their diabetes risk, in the manner of the current bowel cancer screening initiative which aims to reach all adults at age 55 and again at age 65 years.

In this extended study a mail-out to 150 randomly selected adults aged 60 years or older will be utilised, as one of the potential ways of reaching adults at high risk of type 2 diabetes and responses/non response and outcomes recorded and evaluated.

Period of investigation:

Please give expected commencement and completion dates of the investigation.

Commencement date:	1.2.2014	**Completion date:**	31.8.2014

5. REVIEW OF ETHICAL CONSIDERATIONS

Research is only considered to be Low Risk if you answer in the negative to all the following questions. If you answer in the positive, you must complete a full application using the NEAF (National Ethics Application Form)

Is your research a clinical trial? (A clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedure and devices, a preventative procedure or a diagnostic device or procedure)	No √ Yes ☐
Does your research involve the administration of medication or placebo beyond the normal routine care of the participant (if under medical care)?	No √ Yes ☐

Does your research involve an innovation in clinical practice or complementary medicine? (An innovation is defined as a new diagnostic or therapeutic method that aims to improve health outcomes but which has not yet been fully assessed for safety and/or efficacy. The spectrum of innovations may range widely from minor variations or extensions of existing methods to new indications, through to completely novel technologies)	No √Yes
Does your research involve the collection of human tissue samples beyond the normal routine care of the participant (if under medical care)? Human tissue samples include blood and other bodily fluids.	No √ Yes ☐
Does your research involve the use of gametes and/or human embryos?	No √ Yes ☐
Does your research involve the use of human stem cells?	No √ Yes ☐
Does you research involve genetic testing?	No √ Yes ☐
Does your research involve the deception of participants, including concealing the purposes of research, covert observation and/or audio or visual recording without consent?	No √ Yes ☐
Does your research involve the participation of people without their prior consent?	No √ Yes ☐
Does your research involve withholding from one group specific treatments or methods of learning from which they may benefit?	No √ Yes ☐
Does your research involve the access or use of medical records where participants can be identified or linked to their records in some way?	No √Yes
Does your research involve the use of ionising radiation?	No √ Yes ☐
Does your research involve the use of personal data obtained from a Commonwealth or State Government Department/Agency without the consent of the participants e.g. getting a list of addresses from the Australian Electoral Commission?	No √ Yes ☐

Does your research **specifically target** any of the following groups of people; (specifically target means they are the central group of participants, as opposed to potentially being incidentally recruited as part of the general population) • Women who are pregnant and the human foetus • Children and young people • Those highly dependent on medical care who are unable to give consent • People with a cognitive impairment, intellectual disability or mental illness • People who may be involved in illegal activities or residents of custodial institutions • Aboriginal and Torres Strait Islander Peoples • People in other countries • People who are unable to give informed consent because of difficulties in understanding an information sheet (i.e. non English speakers etc)	No √ Yes ☐
Does your research pose any risks for participants under medical care beyond those of their routine care? (Risks include not only physical risks but also psychological, spiritual and social harm or distress eg stigmatisation or discrimination)	No √ Yes ☐
Does your research involve the in depth discussion of any of the following topics whether by interview or as part of a questionnaire or survey; • Parenting practices, • Sensitive personal issues, • Sensitive cultural issues, • Grief death or serious traumatic loss, • Depression mood states or anxiety, • Gambling, • Eating disorders, • Illicit drug taking or substance abuse, • Psychological disorders, • Suicide, • Gender identity and/or sexuality, • Race and/or ethnic identity, • Fertility and/or termination of pregnancy	No √ Yes ☐

Does your research involve the potential disclosure of illegal activities or criminal behaviour?	No √ Yes ☐
Are there any specific risks to the researcher (i.e. will the research involve the use of hazardous materials or be undertaken in a politically unstable area)?	No √ Yes ☐
If your research will take place in an overseas setting do any of the following apply: is the research to be undertaken in a politically unstable area? Does it involve sensitive cultural issues? And/or: will the research take place in a country in which criticism of the government and institutions might put participants and/or researchers at risk?	No √ Yes ☐
Does your research explore potentially confidential business practices or seek to elicit potentially confidential commercial information from participants?	No √ Yes ☐
Does your research explore potentially divergent political views or involve the collection of politically sensitive information?	No √ Yes ☐

5. FUNDING

Under the National Statement (2.2.6) a researcher must disclose:

- *the amount and sources or potential sources of funding for the research; and*
- *financial or other relevant declarations of interest of researchers, sponsors or institutions*

Do the investigators have any financial interest in this project? No √ Yes ☐

If this Application relates to a Grant(s) and/or Consultancies, please indicate the title and Number relating to it:

Funding Body:	Amount:
Funding Body:	Amount:

If no external funding has been obtained, please indicate how any costs of research will be met: Costs covered by industry partners through in-kind contribution.

6. RECRUITMENT

Selection of subjects

There will be two (2) recruitment processes for participants in this study/trial

1. The initial selection of adults to complete the AUSDRISK will be from the two primary healthcare services (one in the public health sector, the other in the private health sector) plus those adults aged 60 years and over who receive an AUSDRISK via the mail-out.
2. The second selection will be those subjects from the two primary healthcare sectors and the mail-out who scored in the High Risk range on the AUSDRISK. They will be invited to participate in the follow-up component of the study.

Initial recruitment:

- Mail-out – random selection of 150 adults aged 60 years and over will receive an AUSDRISK assessment form with information regarding the trial and request to complete the AUSDRISK and an invitation to participate in a follow-up if scoring in the High Risk range.
- Private healthcare sector - Clients aged 45 years and over attending for a full eye examination with pupil dilatation at three Optomeyes® group optometry practices in Southern Tasmania will be invited by their treating optometrist to participate. The commencement age for recruitment was recommended by the participating optometrists who advised that the through-put for full eye assessments was low for adults under the age of 45 years, along with the relatively lower type 2 diabetes risk in the younger age groups.
- Public healthcare sector - All new adult patients (adults 18+years) attending for health services conducted at the Clarence Integrated Care Centre (CICC), Bellerive, Tasmania will be invited by the CICC admission staff and their treating health professional to participate. The wider age range chosen for the new patients at Clarence Integrated Care Centre (CICC) is due to the CICC management wishing to trial the process of AUSDRISK implementation as a regular component for ALL new patient assessments.

There are no gender criteria and the age range chosen is mainly reflective of the 2013 registration of adults with type 2 diabetes, on the National Diabetes Services Scheme (NDSS) database in Tasmania.

As at 31st May 2013 there were 21,728 adults over the age of 20 years with type 2 diabetes 11,527 males and 10,201 females.

As indicated in the figures below there is low prevalence of type 2 diabetes in adults aged less than 40 years. Finding a cohort of 100 people scoring at High Risk on the AUSDRISK is unlikely in the younger ages range.

	21-39 yrs	40-49 yrs	50-59 years	60–69years	70-79years	80-81years	90+years	
Male	225	860	2244	3676	2978	1370	174	11 527
Female	358	983	1812	2777	2500	1456	314	10 201
Total	583	1843	4056	6453	5478	2826	488	21 728
Percentage	2.68%	8.57%	18.67%	29.69%	25.21%	13.0%	2.25%	100%

Recruitment of subjects

Following extensive discussion of the AUSDRISK trial aims and processes between the researcher and the managements of the Clarence Integrated Care Centre and the Optomeyes® optometry practices in southern Tasmania both organisations have agreed to participate in this AUSDRISK trial. Both organisations participated in the initial pilot study of the AUSDRISK implementation in 2011-12.

All health professional staff members will be provided with written protocols to follow for introducing the trial and inviting the clients to participate (see documentation attached).

All participants will be provided with an AUSDRISK 'package' in which is included:

- a Participant Information Sheet;
- a Consent Form to participate in the trial;
- an AUSDRISK assessment form;
- a paper tape measure and instructions on how to measure waist circumference

Optomeyes® clients:

All adult clients aged 45 years and over (not previously diagnosed with diabetes) attending for a full eye examination with pupil dilation at three Optomeyes® optometry practices (private health sector) in Southern Tasmania will receive a personal invitation from their optometrist to participate in the AUSDRISK trial. The optometrists, trained to implement the standardised introduction procedure (see attached Implementation of AUSDRISK Assessment tool at Optomeyes®) will explain the AUSDRISK trial and hand an AUSDRISK package to the client. The client will be invited by the optometrist to read the information sheet; provide consent to participation in the trial by signing the consent form and to complete the AUSDRISK. Each client will complete the AUSDRISK assessment procedure prior to the dilation drops dilating their pupils (as part of the full eye health assessment) and return the completed form back to the optometrist to check their AUSDRISK score.

Clarence Integrated Care Centre (CICC) new patients:

All New adult Patients (adults 18+years not previously diagnosed with diabetes) attending for health services at the Clarence Integrated Care Centre (CICC), Bellerive, Tasmania will be advised by a Front Desk administration officer trained in AUSDRISK Implementation at CICC, that the CICC is conducting a trial implementation of the AUSDRISK as part of its new patient assessment. All new patients will be invited to complete an AUSDRISK as part of their New Patient admission process. The AUSDRISK 'package' will be handed to them. Each new patient will be invited by the Administration Officer to read the Information Sheet; provide consent to participation in the trial by signing the Consent Form; complete the AUSDRISK and take it with them to their appointment with an Allied Health professional who will check their AUSDRISK score (see attached Implementation

protocol).

Mail-Out

Mail-out – An AUSDRISK assessment form with instructions on completion will be mailed out to a random selection of 150 adults aged 60 years and over in Southern Tasmania. Recipients will be invited to participate in an AUSDRISK trial being conducted by the University of Tasmania. Included in the mail-out will be the AUSDRISK 'package' and a Reply Paid pre-addressed envelope.

All mail-out recipients will be requested to return the documentation either completed or not completed to the addressee on the Reply paid envelope.

Information about subjects **Which of the following best describes the identifiability of the data (including tissues) collected?**	
Non-identifiable data (which has never been labelled with individual identifiers, or from which identifiers have been permanently removed, and by means of which no specific individual can be identified)	√
Re-Identifiable (from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets)	
Identifiable (where the identity of a specific individual can reasonable be ascertained. Examples of identifiers include the individuals name, image, date of birth or address).	√☐

If the information is Re-Identifiable or Identifiable, please give details of the information that will be collected. Also indicate how the confidentiality and anonymity of the participants will be protected:

Participants who score in the High Risk range and consent to being followed up by telephone interview or email survey will be requested to supply their contact details. All personal information and data will be kept secure – see data storage information p 17.

Analysis and reporting of data from all participants will be de-identifiable.

6. RELEVANT LITERATURE REFERENCES

Please list the most relevant and recent literature references, both by the investigator and/or by others, that support the justification for the study.

AUSDRISK assessment tool:

Chen L, Magliano D, Balkau B, Colagiuri S, Zimmet PZ, Tonkin AM, Mitchell P, Phillips PJ, Shaw JE. AUSDRISK: an Australian Type 2 Diabetes Risk Assessment Tool based on demographic, lifestyle and simple anthropometric measures. Med J Aust. 2010 Mar 1; 192 (4):197-202.

Pasco JA, Kotowicz MA, Henry MJ, Nicholson GC. Evaluating AUSDRISK for predicting incident diabetes in an independent sample of women. Med J Aust. 2010 Sep 20; 193 (6): 374.

Wong KC, Brown AM, Li SC. AUSDRISK – application in general practice. Aust Fam Physician 2011 Jul; 40 (7): 524 – 6.

Comino EJ, Harris MF, Shaw JE, Jayasinghe UW. Detection of type 2 diabetes: what role for associated risk and protective factors and socioeconomic status. Aust Health Rev. 2012 Aug; 36 (3): 349-55.

Davis-Lameloise N, Hernan A, Janus ED, Stewart E, Carter R, Bennett CM, O'Reilly S, Philpot B, Vartiainen E, Dunbar JA. The Melbourne Diabetes Prevention Study (MDPS): study protocol for a randomized controlled trial. Trials 2013, 14:31 http://www.trialsjournal.com/content/14/1/31

Diabetes Screening:

RACGP Guidelines for Diabetes Management in General Practice 2013/14.

National Evidence Based Guideline for Case Detection and Diagnosis of Type 2 Diabetes 2009 (current)

Sargeant LA, Simmons RK, Barling RS, Butler R, Williams KM, Prevost AT, Kinmonth AL, Wareham NJ, and Griffin SJ. Who attends a UK diabetes screening programme? Findings from the ADDITION-Cambridge study. Diabet Med. 2010 September; 27(9): 995–1003.

Klein Woolthuis EP, de Graw WJ, van Gerwen WH, van den Hoogen HJ, van de Lisdonk EH, Metsemakers JF, van Weel C. Screening for type 2 diabetes in primary care using a stepwise protocol: the Diabscreen Study. Primary Care Diabetes. 2007 Dec;1(4): 199-202

Optometry:

Crawford TN, Alfaro DV 3rd, Kerrison JB, Jablon EP. Diabetic retinopathy and angiogenesis. Curr Diabetes Rev. 2009 Feb; 5(1): 8-13.

Curtis TM, Gardiner TA, Stitt AW. Microvascular lesions of diabetic retinopathy: clues toward understanding pathogenesis? Eye (Lond). 2009 Jul; 23 (7): 1496-508. Epub 2009 May 15.

Jackson GR, Barber AJ. Visual dysfunction associated with diabetic retinopathy. Curr Diab Rep. 2010 Oct; 10 (5): 380-4.

Morello CM. Etiology and natural history of diabetic retinopathy: an overview. Am J Health Syst Pharm. 2007 Sep 1; 64 (17 Suppl 12): S3-7.

Howes JH et al. Screening for diabetes in unconventional locations:- Resource implications and economics of screening in optometry practices Health Policy 102 (2011) 193-199

7. PROCEDURES

Adult clients attending practices in two primary healthcare sectors (one in the private health sector and one in the public health sector) will be recruited to complete an AUSDRISK assessment by their treating health professionals (as per *Recruitment of Subjects*).

It is expected that recruitment in the two primary healthcare sectors will continue over a period of six months or until fifty (50) clients/patients scoring in the High Risk category in each of the sectors (total 100 High Risk) have consented to participate in the follow-up component of the study.

The AUSDRISK assessment form will be mailed out to 150 adults over the age of 60 years in the Southern Tasmania region (random selection). The mail-out will be linked to the mail-out of Seniors' Cards. The researcher will have no involvement in this process apart from providing the "AUSDRISK package".

All participants will receive information on the study with instructions on how to complete the AUSDRISK. All participants will be required to provide written consent to participate in the study. See protocols attached.

Those who have scored in the High Risk range on the AUSDRISK will be invited to participate in the follow-up segment of the study. They will have the opportunity to agree or not agree to participate by the choice of providing (or not) their phone or email contact details.

Approximately 6 weeks after completion of the AUSDRISK, a UTAS researcher will conduct a standardised phone interview or send an electronic survey (see interview questions attached) to those clients (from all sectors) scoring in the High Risk range who have given their written consent and provided contact details (phone/email).

The interview schedule template/electronic survey will be available electronically and participant responses will be added during the phone interview or online via email survey. All responses will be held in securely with access only via password on a computer hard drive. Printed copies will be stored in a locked cupboard with access only via a key held by a designated person (UTAS researcher).

Clarence Integrated Care Centre – with new patients as part of their initial assessment,

All front desk administration staff and all Health Professionals at CICC will be trained to implement the AUSDRISK as per protocols attached.

The AUSDRISK trial will be introduced to all New Patients by the front desk admission staff and,if the patient has not previously been diagnosed with diabetes, an AUSDRISK 'package' will be handed to them.

New patients will be invited by the Administration Officer to read the information sheet; provide consent to participation in the trial by signing the consent form; and complete the AUSDRISK.

New patients will complete the AUSDRISK prior to attending their appointment with the Health Professional and take the completed AUSDRISK plus all trial documentation to their appointment.

Health Professionals will check that the AUSDRISK documentation has been completed and write the TOTAL score on the AUSDRISK form and on the front of the Information sheet.

Health professionals will emphasise that the AUSDRISK assessment tool provides an assessment of risk for developing diabetes it is NOT a diagnostic tool. Only a medical practitioner can diagnose diabetes.

- If the AUSDRISK score is less than 12 points, the Health Professional will advise the patient to follow the instructions on the AUSDRISK assessment tool.
- If the AUSDRISK score is 12 points or more, the health professional will discuss the follow-up component of the study for those who score in the High Risk range. The patient will be advised that participation is voluntary and should indicate on the consent form whether they (client)'AGREE' or "DO NOT AGREE" for follow up. If they 'AGREE', they will provide their contact details.
- Health professionals will check that the AUSDRISK total score and the patient's age, gender and family history for Type 2 diabetes are written on the front of the Information sheet.

Health Professionals will place the AUSDRISK trial documentation for each new patient, irrespective of AUSDRISK score and whether patient agrees to further participation, (Information sheet; Consent Form and Information sheet for those patients scoring in the High Risk range) in an envelope; seal it and place it in a sealed container (see Data storage details). The patient will retain their completed AUSDRISK assessment tool either to take to a medical practitioner for a biomedical assessment or for future health assessments.

Optomeyes® - clients having a full eye health assessment

During the first part of the full eye health assessment, the optometrist will check the client's diabetes status and if the client has not been diagnosed with diabetes, the optometrist will introduce the AUSDRISK to the client, and emphasize its relationship to eye health and diabetes.

The optometrist will hand the AUSDRISK 'package' to the client and explain the details and rationale (as per the Optometry Implementation form) and check that the client is willing to participate in the AUSDRISK assessment.

The optometrist will emphasise that the AUSDRISK assessment tool provides an assessment of risk for developing diabetes it is NOT a diagnostic tool. Only a medical practitioner can diagnose diabetes.

The optometrist will advise that after the dilating drops are put in the eyes the client will go to the waiting room and during the time prior to the drops taking effect the client is requested to:

Read the Information Sheet and sign the Consent Form to indicate agreement to participate in the trial and complete the AUSDRISK.

It takes approx. 10 minutes for the pupil to dilate so the client's vision is fine to complete the forms.

(This is the advice from the participating optometry group).

- The client will take the completed AUSDRISK and other forms back to the optometrist for the second part of the eye health assessment.
- If the AUSDRISK score is less than 12 points, the client will be advised to follow the instructions on the AUSDRISK assessment tool.
- If the AUSDRISK score is 12 points or more, the health professional will discuss the follow-up component of the study for those who score in the High Risk range. The client will be advised that participation is voluntary and that they should indicate on the consent form whether they (client)"AGREE" or "DO NOT AGREE" for follow up. If they 'AGREE' they will provide their contact details.
- The optometrist will write the AUSDRISK total score and the patient's age, gender and family history for Type 2 diabetes on the front of the Information sheet.
- The optometrist will place the AUSDRISK trial documentation for ALL CLIENTS (Information sheet; Consent Form and Information sheet for those patients scoring in the High Risk range) in an envelope; seal it and place it in a sealed container (as per Data Storage). The client will keep/retain their completed AUSDRISK assessment tool either to take to a medical practitioner for a biomedical assessment or for future health assessments.

Mail-out

An AUSDRISK assessment form with instructions on completion will be mailed out to a random selection of 150 adults aged 60 years and over in Southern Tasmania. The mail-out will be linked to the mail-out of Seniors' Cards. The researcher will have no involvement in this process apart from providing the "AUSDRISK package". Recipients will be invited to participate in an AUSDRISK trial being conducted by the University of Tasmania. Included in the mail-out will be the AUSDRISK 'package' and a Reply Paid pre-addressed envelope. The trial information will include a request to read the Information Sheet and sign the Consent Form to indicate agreement to participate in the study; and instructions to complete the AUSDRISK including the waist circumference measurement; to write the total score on the AUSDRISK brochure and provide details of age, gender and family history on the Information Sheet; and follow the instructions for their score range provided on the AUSDRISK form.- Instructions for those who score High Risk, are to contact their medical practitioner to be considered for a biomedical assessment to determine their diabetes status. Those who score in the High Risk category will have the opportunity to participate in the follow-up telephone interview/electronic survey via email by providing their contact details.

The client will keep/retain their completed AUSDRISK assessment tool to either to take to a medical practitioner for a biomedical assessment or for future health assessments.

All mail-out recipients will be requested to return the documentation (minus the AUSDRISK tool) either completed or not completed to the addressee on the Reply paid envelope.

8. DATA STORAGE

Where will the data be kept?

The data sheets for each client/patient will be placed in individual envelopes and sealed immediately and kept in a locked cupboard in each of the primary healthcare sites during the course of the trial. The UTAS researcher (Liz Bingham) will collect the sealed envelopes each week and on completion of the trial. .

Responses from the primary health care sites and the mail-out will be kept in a locked cupboard at DHHS Population Health where the researcher is employed.

How will the data be kept secure? As above

The data will be kept in locked cupboards with access only via a key held by one designated person at each site and by Liz Bingham at Population Health.

How and when will the data be destroyed?

The data will be shredded 7 years after completion of the project.

Will any personal information be collected from sources other than the subjects themselves (Please refer to Privacy Legislation Section 95A - National Privacy Principles)?
If YES, please declare the sources of the Information i.e. medical records, databases, registries, lists of members from Associations, clubs etc:

No √ Yes ☐ (please detail)

Will data on individual subjects be obtained from any Commonwealth Government agency without seeking the consent of the individuals? *If yes, then please declare which agency and what information is being sought. If you wish to obtain data containing personal information from any Commonwealth Government agency state the names of these agencies, describe the nature of this data and explain the justification for obtaining this information. At the Commonwealth level the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the Privacy Act 1988. The NHMRC requires the HREC to provide information on the cases in which it has approved access to, and use of, data held by Commonwealth Government agencies.*

No √ Yes ☐ (please detail)

11. INFORMATION SHEET

With few exceptions, it is essential that subjects are provided with an information sheet about the study in which they are being asked to participate. The Chair of the HREC will pay close attention to the information that is given.

A copy of the proposed information sheet must be attached to your application form.

Is your proposed Information sheet attached to this application?

Yes √ No ☐ (please provide an explanation as to why)

12. CONSENT FORM

Written evidence of consent is usually required for research involving human subjects. If written consent is to be obtained a copy of the actual consent form that you propose to use. In certain circumstances, the HREC may give approval for consent to be waived (see Chapter 2.3 of the *National Statement*). While written consent is the norm, there are various kinds of studies for which other procedures for obtaining consent are more appropriate (See Chapter 2.2 of *National Statement*).

If you consider that written consent is inappropriate for this project please state your reasons clearly referring to the appropriate sections of the National Statement.

Is a proposed consent form attached to this application?

Yes √ No ☐ (please provide an explanation as to why)

13. APPROVALS FROM OTHER DEPARTMENTS/INSTITUTIONS

Does this project need the approval of any institution other than the University of Tasmania and/or the Department of Health and Human Services (i.e. Department of Education, particular wards in hospitals, prisons, government institutions, or businesses)?

If 'YES', Please indicate below what Institutions are involved and what the status of the Approval.

No √ Yes ☐ (please detail):

Name of Other Institution(s): Status:

Does this project need the approval of any other HREC? If 'YES', Please indicate below which HREC and the status of the application.	No √ Yes ☐ (please detail): Other HREC(s): Status:

14. DECLARATIONS

The Head of School or the Head of Department is required to certify that:

- He or she is familiar with this project and endorses its undertaking;
- The resources required to undertake this project are available;
- The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

If the Head of School/Department is one of the investigators, this statement must be signed by an appropriate person. This will normally be the Head of School/Department in a related area or by the Dean.

Name	
Position	
Signature	
Date	

Conformity with NHMRC Guidelines

The *Chief Investigator* is required to sign the following statement:

I have read and understood the *National Statement on Ethical Conduct in Human Research 2007* and the *Australian Code of Conduct for Responsible Research 2007*. I accept that I, as Chief

Investigator, am responsible for ensuring that the investigation proposed in this form is conducted fully within the conditions laid down in the *National Statement* and any other conditions specified by the HREC.

Name of chief investigator Signature	Assoc. Prof Kate Macintyre
Date	19/08/2013

Signatures of Other Investigators

The other investigators should sign to acknowledge their involvement in the project and to accept the role of the Chief Investigator. – N/A

(Name) Assoc. Prof Kelly Shaw	(Signature)	(Date) 19/08/2013
(Name) Professor J R Burgess	(Signature)	(Date) 19/08/2013
(Name) Liz Bingham		(Date) 19/08/2013

14. DECLARATIONS

The Head of School or the Head of Department is required to certify that:

- He or she is familiar with this project and endorses its undertaking;
- The resources required to undertake this project are available;
- The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

If the Head of School/Department is one of the investigators, this statement must be signed by an appropriate person. This will normally be the Head of School/Department in a related area or by the Dean.

Name

Position

Signature

Date

Conformity with NHMRC Guidelines

The *Chief Investigator* is required to sign the following statement:

I have read and understood the *National Statement on Ethical Conduct in Human Research 2007 and the Australian Code of Conduct for Responsible Research 2007*. I accept that I, as Chief Investigator, am responsible for ensuring that the investigation proposed in this form is conducted fully within the conditions laid down in the *National Statement* and any other conditions specified by the HREC.

Name of chief investigator

Signature

Date 14/8/13

Signatures of Other Investigators

The other investigators should sign to acknowledge their involvement in the project and to accept the role of the Chief Investigator.

(Name) John Burgess (Date) 15/8/13

(Name) Kelly Shaw (Date) 15/8/13

(Name) James Vickers (Signature) (Date) 15/8/13

CHECKLIST	
Please ensure that the following documents are included with your application:	
Information sheet/s (if not attached ensure you have explained why in Section 11)	√
Consent form/s (if not attached ensure you have explained why in Section 12)	√
Questionnaires (if applicable)	√
Interview schedules (if applicable)	√
A copy of any permissions obtained i.e. Department of Education, Other HREC, Other Institutions (if applicable)	N/A
All documents relevant to the study, including all information provided to subjects.	√
Telephone Preambles (if applicable)	√
Recruitment Advertisements (if applicable)	N/A
Email Contents (if applicable)	N/A
Has the 'Statement of Scientific Merit' been signed?	√
Have all investigators signed the form?	√

Follow-up Questions for telephone interview/email survey for people who scored in the High Risk range of the AUSDRISK.

The telephone interview/survey would be conducted by a UTAS researcher approximately 6 weeks after the client had completed the AUSDRISK. At that time the participant had agreed to participate in the follow-up interview by signing the Consent Form and providing their name and contact details.

Interviewer identifies and introduces herself as a UTAS researcher for the AUSDRISK trial. Checks the name of the interviewee and that the interviewee still consents to participating in the telephone interview.

• Q1 –Name - may I check your name • Q2 – Do you still consent to an interview? • • YES	NO, if no – could you advise why it is no longer convenient? Answers Time - ?reschedule No longer interested – are you able to tell me why you are no longer interested?

- If YES

  Interviewer re-iterates the purpose of the follow-up telephone interview:

- To follow-up people who have scored in the High Risk range of the AUSDRISK to find out what actions they had taken or had been able to take in determining their diabetes status.

• Q3 Have you been able to see your GP to discuss further assessment as recommended by the AUSDRISK?	
YES ? Tests Y/N If Y Results of tests Diabetes/pre-diabetes/no diabetes If N (to tests) Any other directions -? Re-test 12/12 Treatment/management options Medication – type Lifestyle –	NO – why unable to see GP so far – write responses Do you plan to see your GP? Y/N If Yes Appointment scheduled? Y/N If No - Plan to see another health/lifestyle professional? Y/N If Appointment scheduled – date – may I contact you after that time?

- Q4 May I just re-check the details you provided when you completed the AUSDRISK
  - Gender
  - Age
  - Family history of diabetes

Thank you for participating in this interview. It is very important to the research that the University of Tasmania, School of Medicine is conducting.

Graduate Research Office
Private Bag 105, HOBART TAS 7001
Tel: 03 6226 8559 Fax: 03 6226 7497

Research Plan

The Research Plan provides the blueprint for a candidate's higher degree by research (HDR) **and must be completed within the first six months** (4 months for Masters, equivalent full time) of candidature. First year candidates are required to prepare with their Supervisory team a Research Plan using this form. In the case of research in the theatrical, musical or visual arts disciplines, the Research Plan may include visual or aural documentation relating to practice-led research development. Candidates must discuss this plan with their supervisors and graduate research coordinator. The Primary Supervisor **must** approve the Research Plan before forwarding it to the Graduate Research Office. A copy of the candidate's plan should be retained by the supervisor for the School's records.

NOTE: If any part of the Research Plan does not comply with disciplinary norms or established guidelines in the enrolling School / Institute / Centre this issue must be discussed with the Graduate Research Co-ordinator or Head of School, prior to submission.

The Research Plan maps the aims, methods, directions and milestones of the degree. By Confirmation of Candidature, which takes place within the first 11 months of full-time PhD candidature (and 7 months for Masters), the Research Plan will have been fine-tuned and any issues affecting progress discussed and addressed within it.

The Research Plan outlines the rationale, research context and structural outline; it includes the entire timetable and forward plan for a candidate's HDR. It considers, where appropriate, issues surrounding ethics, budgetary requirements and access to infrastructure. The Plan is a guiding document, and because the research process is, by its nature, dynamic, it should be continually updated. However, at the end of the first year the Supervisory Team will have settled on a framework that can be modified with new developments and opportunities bearing in mind the overall timeline imposed by maximum candidature.

At the time of the annual review of progress, candidates and supervisors should refer to the Research Plan and indicate how and in what ways it remains valid or must be altered.

All higher degree by research candidates are required to meet with their Primary Supervisor(s) if not all members of their supervisory team as soon as possible and within two weeks of commencement of candidature to discuss their proposed research. The outcome of this meeting should be a draft skeletal outline of the research plan with initial consideration of resources required for the research.

SECTION 1 - CANDIDATE'S DETAILS:

Candidate's name:	*Elizabeth Bingham*	ID Number:	*791688*
School/Institute/Centre: *School of Medicine/UTAS*			

SECTION 2 – RATIONALE FOR RESEARCH PROPOSAL

Rationale for the research may include a brief overview of current knowledge of the topic and a statement/s about the key hypotheses, questions and/or aims of the research

Type 2 diabetes is a metabolic condition that affects between 5 and 8% of the adult population in Tasmania. The condition leads to cardiovascular disease, renal, neurological and ophthalmic complications if poorly controlled. Up to 1 in 2 people with type 2 diabetes do not know they have the condition (i.e. are undiagnosed). The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK) was developed in 2008 to identify those people at High Risk of developing type 2 diabetes(1). AUSDRISK is a simple paper-based screening tool that calculates the numeric risk someone has for type 2 diabetes. People who score 12 points or more on the tool are at High Risk and are advised to attend their General Practitioner to have a biomedical assessment to determine their diabetes status. Since its development, the

AUSDRISK has not been widely used in Australia for population screening of to raise people's awareness of their risk of type 2 diabetes. Little is known as to why there has been poor utilisation of the AUSDRISK. A recent study (2011) amongst GPs in NSW found that only 22% were aware of the AUSDRISK (2) despite the recommendation for its usage as the initial step in screening for type 2 diabetes(3) .
Australia does not have a national screening program for type 2 diabetes, unlike the US, UK, Finland and many other European countries . Type 2 diabetes is clearly an important health problem and as such meets the Australian criteria for the assessment of population screening regarding condition, test, assessment, treatment and ongoing management (4). There is however less clarity around how to best access the target population and increase uptake and follow-up at a population level. The Population Based Screening Framework guidelines suggest that there needs to be a defined target population that can be invited to participate in screening. In addition, the proposed screening program must be feasible and implementations achievable. These are issues that still need to be addressed. This demonstration project aims to determine feasibility, acceptability, uptake and effectiveness of utilising the AUSDRISK in healthcare and non-healthcare settings as the first step in a screening program for type 2 diabetes in Tasmania and potentially nationally.
In February-March 2011, we conducted a 6 week pilot "proof of concept" study for implementation of the AUSDRISK in the Southern Tasmania Health Area. The aim was to test the acceptability and feasibility for both clients and health professionals of implementing the AUSDRISK as part of a health service in two primary healthcare settings - a Community Health Nursing Service in the public health sector and in two optometry practices in the private health sector. Diabetes screening was not part of routine practice in either setting in Tasmania although optometry practices had been used as a setting in Holland (6). Fifty two (52) adult clients aged 35 -65+ years without a previous diagnosis of diabetes voluntarily participated in the pilot study. Forty-eight per cent (48%) of those assessed using AUSDRISK, scored in the high risk category. None of those who scored "high risk" had been previously tested for diabetes. All those identified as high risk stated their intention to follow up with their GP for biomedical assessment. The strengths of the trial showed that the AUSDRISK was easy to administer in these healthcare settings and was acceptable for all participants (clients and healthcare professionals alike), and effectively identified people at high risk for type 2 diabetes. The limitations were that the trial was designed as a "proof of concept" and as such there was no capacity to take the next steps to investigate the client response and follow-up action, nor the action taken by the general practitioners for those who attended for a biomedical assessment.
This extended study will use the same methodology (as pilot study 2011) to implement the AUSDRISK assessment but additional consent for follow-up will be sought from all clients who score High Risk and an additional potential source for implementing the AUSDRISK (a mail-out) will be investigated. To date the AUSDRISK has not been used as a scheduled "mail out" to adults to invite their participation to self-assess their diabetes risk, in the manner of the current bowel cancer screening initiative.
Those clients who score in the High Risk range will be requested to provide contact details and permission to contact them by phone/email some 6 weeks after the AUSDRISK assessment to determine the outcome of their intention to seek biomedical assessment. A cohort of 100 High Risk clients in each of the community healthcare settings and the mail-out, will be followed-up to determine client and GP responses and actions.
- If they had been seen by a GP (Y/N); if they had received biomedical testing(Y/N); if tested, the results of test (diabetes Y/N or pre-diabetes Y/N); GP recommendations to client and ongoing management

SECTION 3 - TIMETABLE

Timetable for the study should aim for submission at approximately 18 months full time (36 months part time) for a Master degree and 36 months full time (72 months part time) for a Doctoral thesis. NOTE: **The maximum period of candidature is 2 years for Masters and 4 years for PhD.**

The timetable should include realistic, sequential milestones indicating content, activities and/or research to be undertaken in preparation for the write-up of the thesis.

Timelines:
Ethics approval – H0013490.
Enrolment of Organisations has been completed - documentation and written permission obtained from THO-S for Clarence Integrated Care Centre; Optomeyes® directors for three Optomeyes® optometry practices; Department of premier and Cabinet for utilisation of seniors' card mail out.
Standardised documentation, and procedures for implementing AUSDRISK screening for type 2 diabetes including participant information sheet, consent forms and health professional instruction sheets have been completed.

Enrolment of Participants – volunteers invited to participate in the study via Information Sheets, by signing consent forms, and providing contact details- for those who score High Risk and agree to participate in the follow-up study.
Intervention –
Week 1 – distribution of AUSDRISK to 500 older adults via a routine Seniors' Card mail out
Week 2 – training Optomeyes® health professionals
Week 3 – Optomeyes® to commence 8 week AUSDRISK intervention
Week 4 – training health professionals and administrative staff at Clarence Integrated Care Centre (CICC)
Week 5 – CICC to commence 8 week AUSDRISK interventionJuly - August 2014
Follow-up – Week 7 – Week 12 -16 (2 months)

Commencement date CICC
Commencement date CICC ESCNS
Commencement date CICC Physiotherapy
Commencement date CICC Continence Service
Commencement date CICC Dietitian Services
Commencement date CICC Oral Health Service

Analysis - 4 months

Reporting 2 months

SECTION 4 - INFRASTRUCTURE

4a What are your current infrastructure needs? Are they being met? If not, please describe what arrangements will be made to meet them. (●) Yes ( ) No

Computer; Email access;Desk;access to photocopier,Telephone

4b Are there additional infrastructure needs you anticipate for future stages of your project? Have these been planned for? Please provide details. ( ) Yes ( ) No

AUSDRISK assessment forms; information and consent forms; replied paid envelopes

SECTION 5 – DETAILED BUDGET INFORMATION

The Research Plan may include a detailed budget appropriate to the research project. This budget should be regarded as indicative, an exercise in financial planning and subject to reasonable annual adjustment in the light of the project's evolution. The intention would be to ensure project costs are compatible with available funds. **The budget is not an automatic entitlement to spend an allocated amount regardless of the changing needs of the project.** Research related expenses might cover: fieldwork, laboratory consumables, additional library services, off-site photocopying, thesis preparation or any other expenses that can be substantiated as a legitimate cost.

TOTAL PROJECT COST: $57 550
Salary: 0.5 FTE Band 6 $45,000 plus on-costs $8,840 = $53,840
IT expenses = $1,200; Project travel = $1,000
Resources: Stationery $300; Postage $750; Printing $500: Total = $ 1,550

SECTION 6 - ETHICS APPROVAL INFORMATION

You need to consider if your project has ethics implications. The UTAS Research Ethics Policy, information and forms for both Animal and Human (Social Science and Health and Medical) research projects are available from the following web site: http://www.utas.edu.au/research/integrity-and-ethics

If you and your supervisor are uncertain about whether ethics approval is required, please call Integrity and Ethics on 6226 1832 to inquire about ethics requirements. If you require ethics approval, your supervisor and Head of School will need to complete an ethics application.

Note: research that requires ethics approval must not commence until approval has been granted. It is University policy that theses cannot be approved for submission to examiners unless all relevant research ethics approvals have been granted.

SECTION 7 - WORK HEALTH AND SAFETY

Please describe how you will manage any work health and safety issues that will need to be attended to in relation to this project. For details, please refer to the Work Health & Safety Policy Policies and Procedures at http://www.admin.utas.edu.au/hr/ohs/pol_proc/index.html

SECTION 8 – SIGNATURES/APPROVALS

Candidate's Signature

I certify that this plan has been discussed with my Supervisors and Graduate Research Coordinator. I have kept a copy of this document.

Candidate:	Date:	28/10/14

Supervisor/s Signature

I certify that this Research Plan complies with disciplinary norms and established guidelines. I have viewed and approved this Research Plan.

Primary Supervisor:	Date:	28/10/14
Co-Supervisor:	Date:	28/10/14
Co-Supervisor:	Date:	28/10/14
Co-Supervisor:	Date:	/ /

Graduate Research Co-ordinator's Signature

I certify that I have viewed and this Research Plan.

Graduate Research Co-ordinator	Date:	28/10/14

Note: You may add any other relevant additional comments or information and send with this document.

Please scan and return the signed Research Plan by email to:

Appendix 6

UNIVERSITY of TASMANIA | FACULTY OF HEALTH

virtual Tasmanian Academic Health Science Precinct

Final Research Report – end April 2015

Title	Improving prevention and early intervention for type 2 diabetes in Tasmania
Funding Amount	
Completion Date	April 2015
Prepared By	Liz Bingham, A/P Kate Macintyre, A/P Kelly Shaw and Prof John Burgess
Research Aims - please provide summary comments for each of the Aims/Deliverables in your original funding application and any other outcomes from your research, if applicable.	• To extend the 2011 "proof of concept" AUSDRISK study (52 participants) by increasing the numbers of adults assessed in primary healthcare settings and including a mail-out to randomly selected adults aged 60 years and over. o *Total AUSDRISK completion – 309 participants (1417 invitations)* o *Primary Healthcare (PH) – 108 participants (217 invitations)* o *Seniors' Card (SC) mailout – 201 participants (1200 invitations)* • To evaluate the response rate to an invitation to participate in a UTAS study of AUSDRISK including follow-up of those who score High Risk (HR), and consent to participate in the follow-up component of the study. • *Overall Participation rate = 21.8% (consistent with initial participation rates in other national screening studies)* • *PH participation rate = 49.77%* • *SC mailout participation rate = 16.77%* • *Follow-up survey* • *Total HR Consent to survey = 144 (46.6%)* • *Total HR Completed survey = 79 (79/144; 54.86%)* • *PH HR completed survey = 11/44; Rate = 25.0%* • *SC mailout HR completed survey = 68/100; Rate = 68%* • ***Summary***

	• *In Primary Healthcare, the initial participation rate was greater than the initial participation rate gained via the Seniors' Card mailout. However the completion rate to biomedical assessment was greater for the Seniors' Card mailout participants than for the Primary Healthcare participants.* • To determine the effectiveness (case finding High Risk), cost-effectiveness and potential of each setting/approach for implementing the AUSDRISK as an/the initial step in a national screening program for type 2 diabetes (2). • *Total cost SC mailout = $3045.19* • *PH cost was administration costs which were absorbed into usual duties* • *Printing information/instruction forms = $1871.19* • *AUSDRISK = free (Australian Government)* ***Setting effectiveness = HR/total AUSDRISK completion*** • *PH effectiveness = 44/108 = 40.74%* • *SC mailout effectiveness = 100/201 = 49.75%* ***Summary HR case finding rate*** • *SC HR case finding rate was greater than the PH case finding rate* • *No cases of Type 2 Diabetes were identified in individuals classified as High Risk by the AUSDRISK* • *Pre-diabetes was diagnosed in 7 of the 79 individuals, classified as High Risk on the AUSDRISK (8.86%)* • *Of those diagnosed with pre-diabetes, 6 were identified via the SC mailout (6/68=8.82%) and one (1/11) was identified via Primary Healthcare (1/11 = 9.09%).* • *PH AUSDRISK distribution spread is local and related to health (illness) services* • *SC AUSDRISK distribution spread is statewide, not related to health services and has greater potential to impact on and identify those older individuals in the general community.* • To investigate the personal and systemic factors which act as facilitators or barriers t o utilisation of the AUSDRISK as a national type 2 diabetes screening program and compare these factors across the three settings. ***Personal factors (all settings)*** – • *Older people have a negative attitude towards type 2 diabetes (DM2);* • *There is limited health literacy and poor knowledge*

	of DM2; *Sample population were ambivalent towards prevention and management of DM2 and risk averse to addressing a potential health problem (males more so than females)* ***Systemic benefits*** *–* • *PH AUSDRISK face-to-face presentation was more effective for initial participation than the mailout due to health professional positive endorsement of screening;* • *The SC mailout was superior (to primary health) in its ability to deliver AUSDRISK questionnaires statewide with its established mailout system; access to the general community and being independent of demands on health professional time.* ***Systemic barriers –*** • *Opt-in participation for completing AUSDRISK (both settings) limited the participation rate, with SC mailout more affected than PH;* • *No current commitment to routine type 2 diabetes screening in PH with community health setting more affected than optometry practices.* • *Format and scoring of AUSDRISK acted as a barrier to older people participating, in that age and gender (particularly male) both unmodifiable risks which scored very high, and older people felt disempowered to investigate further if they had limited opportunity to reduce their risk. Not all diabetes risk questionnaires rate age and gender as high as the AUSDRISK.* ***Barrier - Validity of AUSDRISK questionnaire*** *–* • *AUSDRISK identified individuals at high risk but on biomedical assessment none were diagnosed with diabetes; 7 with pre-diabetes and 36/43 tested as having normal blood glucose levels.* • *AUSDRISK questionnaire allocates high scores for the age and gender risk factors. This may affect the discriminatory capacity of the AUSDRISK to identify diabetes when used with an older population.* • *Lack of consistency in diabetes risk prediction between different diabetes risk assessment questionnaires. Comparing AUSDRISK age and risk*

	factor scores with those of other validated diabetes screening questionnaires revealed some individuals who had been being classified as HR on the AUSDRISK had lower risk ratings for type 2 diabetes than those estimated by AUSDRISK. • To establish a database both quantitative and qualitative for the implementation and outcomes of AUSDRISK screening in different healthcare and non-healthcare settings for type 2 diabetes in Tasmania with a view to implementation of AUSDRISK nationally. • ***Individual and systemic barriers need to be addressed and other methods need to be investigated before continuing with planning to formally embed type 2 diabetes screening assessment using the AUSDRISK into routine clinical practice.***
<u>Funding</u> - please provide summary comments accounting for the expenditure of allocated funds.	**Total Funding** **$ 54,672.50** **Expenditure in T1** Salaries $ 10,407.08 Mail/Postage $ 3,045.19 Printing $ 1,871.19 $ 15,323.46 ***plus* costs not yet in T1** Statistical support $ 5,000.00 K Macintyre salary costs $ 7,758.24 $ 12,758.24 **Total Expenditure** **$ 28,081.70** **ACTUAL FUNDS REMAINING** **$ 26,590.80** ***Please also complete one of the following statements.*** I confirm that all funding allocated to this research has been fully expended on the research activity as outlined in my original funding submission. ***Or*** XX has been expended on this research project. Residual funds of YY will be returned to the Commonwealth.

<u>Publication</u> – please provide summary information on any presentations or publications relating to your vTAHSP research. **Please also append any abstracts, publications, reports, presentations etc that relate to your vTAHSP research.**	Abstract submitted for the Public Health Association of Australia conference September 2015. Draft journal article to be submitted …….to be advised
<u>Translation</u> – please provide summary information on how your research outcomes have been or will be translated or on how the need for translation will be promoted across Tasmania.	***TRANSLATION*** *This study provides valuable insight into the feasibility, uptake and efficacy of implementing the AUSDRISK for the older age group through different settings as well as the follow up of high risk individuals.* *The older age cohort is the most rapidly increasing age-group in Tasmania Currently this cohort has the highest incidence of type 2 diabetes whilst the prevalence of undiagnosed type 2 diabetes and elevated blood glucose is unknown. Both conditions, if untreated lead to a high risk of cardiovascular complications.* *AUSDRISK questionnaire:* *Initial findings indicate that the AUSDRISK questionnaire can be implemented at low cost via healthcare and non-healthcare settings to increase accessibility and improve uptake of to type 2 diabetes screening, for an older cohort. However the uptake rate is low and further consideration should be given to alternative and additional strategies such as opportunistic multiple risk factor screening as part of routine clinical assessment on an opt out basis in the absence of a national screening program.* *Our study results have also shown that there are questions around the validity of the AUSDRISK for diabetes screening in the older age group, which need further investigation prior to any further implementation of the AUSDRISK.*

	Further Research **Investigate the validity and appropriateness of AUSDRISK for type 2 diabetes screening in an older age cohort** • *Review the literature on prediction models to estimate future development of type 2 diabetes, with particular reference to individuals in the 55+years age group.* • *Review and compare the scoring on the AUSDRISK and the FINDRISC or CANRISK and other type 2 diabetes prediction models for similar populations, which have reduced emphasis on age and gender as non-modifiable risk factors.* • *Determine if the AUSDRISK is the most appropriate screening questionnaire for the older age cohort* • *Investigate the effectiveness, advantages/disadvantages of other diabetes risk questionnaires (particularly those with less emphasis on age and gender) and other methods of screening such as point of care testing for HbA1c – for impact, effectiveness, cost and settings.* • *Conduct focus groups with community groups of older people for feedback on acceptability of completing the AUSDRISK in comparison with other risk screening questionnaires eg CANRISC and/or FINDRISC.* • *Increase the participation rate by adding a diabetes information leaflet (FAQs) along with the AUSDRISK to improve knowledge and benefits of effective prevention and management of type 2 diabetes.* ***Promote need to implement diabetes risk screening in Tasmania*** • *Liaise with Diabetes Tasmania to discuss having a more positive approach to the value of older people knowing their blood glucose level and if high, providing strategies to reduce it. Take a more positive approach to show the value of early identification of diabetes and promote the "good news" stories of effective management of diabetes. Reduce the strongly "negative" view that is currently held.* • *Liaise with GPs and GP organisations to promote a more educative and collaborative approach with patients to diabetes risk screening, prevention and management.* • *Seek GP champions to promote this collaborative approach.* • *Liaise with State health organisations in their promotion of improve health literacy particularly in the older age group.* • *Liaise with Diabetes Tasmania re reviewing literacy standards for diabetes information on screening, prevention and*

	management of type 2 diabetes. • *Promote the potential for diabetes screening to be included routinely in all new patient assessments in community health centres.* • *Investigate the potential for optometrists to implement the AUSDRISK for all clients over 45 years having a full eye assessment.* • *Utilise the Seniors' Card mailout to provide information about the benefits of effective prevention and management of type 2 diabetes*
<u>Evaluation</u> - please provide a short evaluation of your research projects overall success.	To our knowledge this is the first study in Australia to implement the AUSDRISK type 2 diabetes risk questionnaire in the older age group 55 to 75+ years. The AUSDRISK questionnaire was distributed to 1417 older adults via face-to-face interviews as part of a healthcare assessment and via a well-established Seniors' card mailout. A total of 401 older adults (28.3%) responded to the initial invitation to participate, of whom 65 had diabetes and were ineligible to participate and 27 subsequently chose to withdraw. The total of 309 older adults (21.8%) completed the AUSDRISK questionnaire. Of those who completed the AUSDRISK, 144 individuals (10.16%) scored in the High Risk (HR) range (≥12 points); 152 (10.7%) scored in the Intermediate Risk range (6-11 points) and 12 (0.8%) scored in the Low Risk range (5 points or less). 6-8 weeks after completion of the AUSDRISK all those who scored High Risk (HR) on the AUSDRISK were invited to participate in a short follow-up survey, to document their actions to being advised of their high-risk status. 76 HR participants completed the follow-up survey, 44 of whom attended their GPs for biomedical assessment and all but one had blood tests. The HR diabetes risk status on AUSDRISK did not reflect the current glycaemic status of the participant. No HR participant was diagnosed with diabetes, but 7 HR participants were diagnosed with elevated blood glucose. The poor initial response rate indicated that completion of the AUSDRISK alone was not sufficient to encourage older people to participate in diabetes pre-screening and survey results highlighted the individual and systemic barriers to completing biomedical assessment in order to achieve effective implementation. Furthermore the results indicated that the validity of the AUSDRISK, when used in an older population, needed further investigation before proceeding with future AUSDRISK diabetes screening in this cohort. This study has established baseline findings for implementing

	AUSDRISK in the older population. In addition to resolving the specific issue of validity with AUSDRISK, we need to address the individual and systemic barriers and investigate other methods before continuing to plan for formally embedding type 2 diabetes screening assessment into routine clinical practice.
<u>Media</u> – please indicate if you would be willing to be involved in media and communications on behalf of the project over the next twelve months.	Yes

SCREENING OLDER ADULTS FOR TYPE 2 DIABETES: MORE THAN AUSDRISK

Elizabeth Bingham, Kate Macintyre, Kelly Shaw, John Burgess
University of Tasmania & Department of Health & Human Services, Hobart, Tasmania.

AUSTRALIAN TYPE 2 DIABETES RISK ASSESSMENT TOOL

OLDER ADULTS

- YOUNG - OLD = 60 - 74 YEARS
  - MID-OLD = 75-84 YEARS
  - OLD-OLD = 85+ YEARS
- No national screening program for type 2 diabetes

1

Why screen "young-old" adults for T2DM?

- Ageing is an independent risk factor for type 2 diabetes (T2DM).
- Rapidly increasing older age population with increasing longevity.
- Screen for early identification, monitoring and management of those with or at high risk of T2DM
- Currently no Medicare-supported T2DM screening for adults aged 50-74 years.

2

How to reach "young-old adults …..

- Continue opportunistic screening via GPs
- Utilize existing systems within public/private health or non-health sectors.
- AUSDRISK – health assessments of new patients.
- Include AUSDRISK with Seniors' Cards (96,000) in Tasmania. Regular statewide mail-out new/renewed cards every 4-6 weeks.

3

AUSDRISK Summary Results

	All settings	Health Centre (Low SES)	Optometry (Well adults)	Seniors' Card (Random mail)
Total distribution	1417	177	40	1200
T2DM	65	= 28 (15.8%)	=13 (32.5%)	= 24 (11.88%)
Participants	309 (21.8%)	= 81 (45.8%)	= 26 (67.5%)	= 202 (16.83%)
Active Decline	135 (9.5%)	= 68 (38.4%)	= 0	= 67 (5.6%)
Nonresponse	908 (63.5%)	= 0	= 1	= 907 (75.0%)
Participants	309	= 81	=26	= 202
High Risk (>12)	144 (46.6%)	= 32 (39.5%)	=12 (46.15%)	= 101(50.0%)
HR Survey	76 %	= 10 (31.3%)	= 3 (25.0%)	= 63 (62.4%)
Attend GP	43 %	= 7 (21.9%)	= 0	= 36 (35.6%)
Blood tests	42 %	= 7		= 35
Normal BG	35 %	= 6		= 29
Elevated BG	7 %	= 1		= 6
T2DM	0%	= 0		= 0

4

AUSDRISK Seniors Mailout

- AUSDRISK distribution to 1417 young - old adults;
- 309 participants
- High Risk: 144 participants
  - 76 HR participants completed 6 week follow-up survey
    - 43 HR had attended GPs for biomedical assessment
    - 42 HR had blood tests
    - 35 HR had normal blood glucose levels
    - 7 HR had elevated blood glucose
    - No HR participant diagnosed with diabetes

5

AUSDRISK High Risk Survey Issues

- Young-old adults
  - ambivalent attitudes towards screening and T2DM
  - unaware of "increasing age" and "male gender" as independent risk factors for T2DM – so don't see relevance
  - don't understand concept of "risk" and "ongoing risk".
  - ? health literacy /knowledge of Diabetes
- General Practitioners
  - ? inadvertently supporting older patients' beliefs
  - ? few incentives to monitor High Risk ($)
- AUSDRISK implementation in "young-old" cohort (60-75 years)
  - ? validity of AUSDRISK for T2DM risk in "young-old" group
  - ? AUSDRISK structure and ?HR advice inhibits participation

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Appendix 8 page308

Improving prevention and early intervention for type 2 diabetes in Tasmania

virtual Tasmanian Academic Health Science Precinct research Report 2015

Introduction

Type 2 diabetes is a current major public health problem. The number of people with DM2 is increasing in every country (International Diabetes Federation Diabetes Atlas sixth edition 2013)[1]. Worldwide there are 387 million people living with diabetes; by 2035 the number is expected to rise to 592 million; 179 million are undiagnosed (IDF atlas 2014).

An estimated 1.7 million Australians have type 2 diabetes. This number is predicted to increase to 3.3 million by 2031. A further 2 million have pre-diabetes which puts them at high risk of developing type 2 diabetes and associated complications (ref [2])

In Tasmania, there are over 22,000 individuals with type 2 diabetes and an estimated 10 000 people with undiagnosed type 2 diabetes and additionally over 45,000 Tasmanians with pre-diabetes – a condition which, if not identified and well-managed puts them at high risk for developing type 2 diabetes (Ref [2]).

The high prevalence of Type 2 diabetes is attributable to both genetic and environmental factors - older age, a family history of diabetes, high blood glucose, hypertension, low HDL-C, obesity, insufficient physical activity and smoking.(Refs)

Diabetes is the leading cause of kidney failure, non-traumatic lower limb amputations and blindness and is a major cause of cardiovascular diseases.

Prevention and management of type 2 diabetes and its precursor condition pre-diabetes is a global, national, and local challenge.

The highest prevalence of type 2 diabetes is in the older age population and is driven in part by an absolute increase in the incidence among those aged 60 years and older due to ageing effects on the pancreatic β cell function, β cell mass, insulin secretion and insulin sensitivity and environmental factors such as rising rates of obesity, and increasing sedentary behavior often caused by other chronic conditions associated with ageing such as arthritis[4].

The flow-on effect of this glycaemic dysfunction (pre-diabetes, type 2 diabetes) is not benign and increases the immediate risk for other age-related conditions such as cancer, cardiovascular diseases and Alzheimer's Disease and reduces the quality of life in the older age group.

Type 2 diabetes is symptomless in the early stages of the condition and has few unique symptoms even when well established.

Tasmania has the oldest population of all states and territories and nationally, and the number in the 60 plus age cohort is increasing more rapidly than the young and mid-age groups. In Tasmania, the highest incidence of newly diagnosed type 2 diabetes is in the older age groups where the newly diagnosed incidence in the 50-59 year group is 23%; in the 60-69 year group is 30% and in the 70–79 year group is 17%[2]. It is unknown how many in the mid- older age group would be at high risk for type 2 diabetes or pre-diabetes but undiagnosed due to the symptomless nature of the glycaemic dysfunction and there being no system within the public health system for diabetes risk assessment.

Type 2 diabetes is clearly an important health problem and as such meets the Australian criteria for the assessment of population screening regarding condition, test, assessment, treatment and ongoing management.

However, Australia, unlike most European countries, UK and the US, does not have a national screening program for type 2 diabetes. The NHMRC Evidence-based Guidelines for the Detection and Diagnosis of Type 2 diabetes in Australia (2009)[5] recommend that a 2 stage targeted screening approach be utilized to identify those people at high risk for developing type 2 diabetes. The first stage is a pre-screening stage to identify individuals at High Risk for developing diabetes or pre-diabetes. The second stage occurs after the High Risk status is identified when individuals would then be advised to see their medical practitioner for a biomedical assessment of their diabetes status. This targeted screening approach widely used by other countries, has not been used systematically on a national basis in Australia.

The Australian Government provides Medicare funding on a limited basis for type 2 diabetes screening of people aged 40 – 49 years who score High Risk on the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)[6].

The major unresolved issues for implementing a national screening program for type 2 diabetes include defining a target population to be screened; how best to access the target population; and how to increase uptake and follow-up for screening.

Development of AUSDRISK

- a pre-screening questionnaire to determine diabetes risk.

The first national Australian Diabetes Obesity and Lifestyle Study (AUSDIAB) was conducted in 1999 - 2000 and its 5 -year follow-up study of 70 percent of the original cohort AUSDIAB-2. Both studies gathered biomedical and lifestyle data from a stratified sample of 11,247 Australians aged 25 years or over in 42 randomly selected urban and non-urban areas of the six states of Australia[7].

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK), based on the findings of the AUSDIAB and AUSDIAB-2 studies, was developed in 2008 as a screening tool to identify those at High Risk for developing type 2 diabetes[8].

The AUSDRISK has been validated as a predictor of diabetes risk at 5-year follow-up and has been acknowledged internationally as a valid and reliable pre-screening test to identify people at High Risk for developing type 2 diabetes[9].

The AUSDRISK is a simple paper-based screening tool. Risk factors for type 2 diabetes are each given a weighted numeric value and the total of the Risk Factor points provides an estimate of the risk for an individual's development of type 2 diabetes over a 5year period. The quantified total risk levels are designated Low, Intermediate and High. Within the High Risk range (≥ 12 points) there are three categories reflecting increasing risk of developing Type 2 diabetes - HR1 =12-15 points (approximately 1 in 14 will

develop diabetes); HR2 = 16-19 points (approximately 1 in 7 will develop diabetes) and HR3 = 20 points or more where the risk is that 1 person in every 3 will develop diabetes. People scoring High Risk are advised to attend their General Practitioner for a biomedical assessment of their diabetes status. However, most General Practitioners identify the diabetes status of individuals via opportunistic screening and rarely utilize the AUSDRISK[10].

Although recommended by the NHMRC Guidelines, the AUSDRISK has not been used for population screening. To date it has only been used for health promotion initiatives to raise diabetes awareness and also to provide the criteria for inclusion of HR participants in a small number of diabetes prevention programs for individuals aged 40 – 49 years in some Australian states but not Tasmania.

In Tasmania, the AUSDRISK has been used infrequently for health promotion activities only.

In 2011, a 6 - week trial in Southern Tasmania showed the AUSDRISK questionnaire could be effectively implemented into non-medical settings - a community nursing service and three optometry practices, and it identified participants at high risk. The AUSDRISK was incorporated as part of an assessment for new patients receiving wound care in the nursing service and in the optometry practices for clients having a full eye assessment including pupil dilatation. Those identified as High Risk stated their intention to seek biomedical assessment but the trial did not allow for this issue to be tested.

This current study sought to increase the numbers (sample) of mid-older people in the target population; to determine effective methods to reach this adult group; and to identify the diabetes risk status of mid-older age respondents. The study also sought to document the responses of those scoring High Risk (HR -12+ points) by inviting them to complete a follow-up survey to identifying their actions to the recommendation that they seek biomedical assessment to determine their diabetes status.

Whilst this study used the same sites and methodology as the 2011 pilot study to implement the AUSDRISK, the number of participants was increased by inviting new patients from a wider range of services within the Community Integrated Care Centre service; inviting patients having a full eye assessment at the same optometry sites, and inviting participants aged 60 years and over via three Seniors' Card statewide mail-outs to investigate the potential to reach older adults who may or may not be attending General Practitioners or health services on a regular basis.

Objectives

We had three main objectives in this study. First, to determine the feasibility and acceptability of implementing the AUSDRISK in non-medical settings in order to identify older individuals at High Risk for developing diabetes. Secondly, to determine the uptake and effectiveness of the AUSDRISK by following the actions of those assessed as being at High Risk, (and those of their General Practitioners) to the older individual being advised to seek biomedical assessment of their glycaemic status. Finally, to review knowledge (health literacy) and beliefs about Type 2 diabetes, held by those recently assessed as High Risk for this condition.

Design, setting and participants

The AUSDRISK study was conducted over a 7-month period in 2014 (April/ May – mid November) in Tasmania, Australia, at a public health Community Integrated Care Centre (CICC), two private optometry practices in Southern Tasmania and via three statewide mail-outs of the Tasmanian Government Seniors' Card[11].

This study received Ethics Approval (H0013490) from the Human Research Ethics Committee (Tasmania) Network. In addition the study received approval from the Tasmania Health Organization South (THO-S) Research Governance Committee (for the CICC); the management of *OPSM/Optomeyes* optometry group and the Tasmanian Government Department of Premier and Cabinet (DPaC), Seniors' Bureau Manager for the mail-outs.

Study design

Cross sectional survey and follow-up using the AUSDRISK type 2 diabetes risk assessment questionnaire.

Participants

The AUSDRISK questionnaire was distributed to 1717 adults, as part of a routine new patient assessment process in two community healthcare settings- one in the public health system – a Community Integrated Care Centre (177 participants) and two optometry practices in the private health sector (40 participants). In addition, the AUSDRISK was included with an instruction/consent form and a pre-paid envelope in three Seniors' Card mail-outs (1500 potential participants) to eligible adults aged 60 years and over, with an invitation to participate and self-assess their diabetes risk

status. The cost per mail-out to 500 potential participants was $1600.00. Consent was obtained from all participants who completed an AUSDRISK. All those who scored High Risk (12 points or more) on the AUSDRISK were invited to participate in a short follow-up survey, 6-8 weeks after completion of the AUSDRISK. The survey took approximately 5 minutes to complete and comprised eight questions relating to the HR participant follow-up actions and biomedical results, and was completed either by phone or on the web via Survey Monkey.

Exclusion criteria

Exclusion criteria for participants recruited via the health service settings included any new patient admitted for community palliative care treatment at home; cardiovascular diseases or neurologic diseases that would compromise one's ability to participate in the study; being pregnant; being unable to reliably understand the English language; having been diagnosed with diabetes (any forms).

Participants recruited via the Seniors' Card mail-outs were advised via the AUSDRISK Study Information Sheet that being diagnosed with any form of diabetes was the only exclusion criteria.

Materials

The AUSDRISK -Australian Government Department of Health and Ageing. The Australian Type 2 Diabetes Risk Assessment Tool. Canberra: DoHA 2008. Available at www.health.gov.au/internet/main/publishing.nsf/Content/diabetesRiskassessmentTool (accessed 3 March 2015)

Follow-up survey

All those who scored High Risk were invited to participate in a short follow-up survey, 6-8 weeks after completion of the AUSDRISK. The survey took approximately 5 minutes to complete and comprised eight questions relating to the HR participant follow-up actions and biomedical results, and was completed either by phone or on the web via Survey Monkey.

Provider training

In each setting, at least one staff member was designated and trained (by LB) to be the clinical/administrative coordinator of the AUSDRISK project. Community Service Officers (CSO) manage all new patient admission for the Community Integrated Care Centre (CICC). Thus the CSO Team Leader and her deputy were best placed to introduce the AUSDRISK questionnaire and were trained accordingly.

Procedure

Community Integrated Health Centre:

Over an eight-week period in July-August 2014, the CSO Team Leader and her deputy advised all new patients that the CICC was conducting a trial of the AUSDRISK questionnaire with a view to incorporating it on a regular basis as part of the New Patient Assessment. Typed and laminated administrative procedures for implementing the AUSDRISK were used to ensure reliability. The AUSDRISK was described to each new patient as a questionnaire for assessing a patient's risk for developing type 2 diabetes; it was a risk assessment not a diagnosis of diabetes, that (diagnosis) could only be done by

a GP. If the client had diagnosed diabetes (either type 1 or type 2) they were ineligible to participate. This was recorded on an instruction sheet and retained.

For all eligible patients the CSO team leader/deputy checked that the new patient could read and understand English language and advised that the patient could seek assistance from the TL/D or an accompanying friend/relative if the patient reported any difficulties. During the trial period all new patients were invited to participate. Participation was voluntary. The team leader/deputy handed a clipboard on which an AUSDRISK questionnaire, an instruction/reporting sheet/consent form, a paper tape measure and a biro were attached. The team leader/deputy (TL/D) asked the new patient to read the instructions; sign the Consent Form after having the reason for this explained; and complete the AUSDRISK questionnaire, including taking a waist measurement. After the AUSDRISK was completed the TL/D checked that all questions were answered; checked the waist measurement; checked the points total; checked that the patient had written their age, gender, familial risk and points total on the front of the instruction sheet and that the consent form had been signed to agree to participation and permit the researchers to use the de-identified data. Those patients who had scored in the High Risk range were reminded of the AUSDRISK recommendation that they contact their GP for blood testing to determine their diabetes status, and then the TL/D asked if they would participate in a short 8-10 question follow-up survey to be conducted in 6-8 weeks. If they agreed, they needed to provide additional signed agreement and their preferred contact details (phone/email). All participants were advised to keep their completed AUSDRISK questionnaire and

those scoring HR were advised to take their completed AUSDRISK questionnaire to their GP. The completed Instruction sheet/consent form was collected by the TL/D and kept in a locked cupboard. On completion of the admission procedures and the AUSDRISK questionnaire, the new patient progressed to the first treatment session. At a convenient point in the treatment session, the Health Professional (HP) concerned reinforced the importance of knowing your diabetes risk status and if it were High Risk, the Health Professional would reiterate the importance of the patient attending their GP for biomedical assessment. The Health Professionals were not prepared to participate in the actual administration of the AUSDRISK as they considered this to reduce their treatment time with the patient.

Optometry practices

In the optometry practices, the optometrists provided an explanation and presentation of the AUSDRISK questionnaire at a time deemed suitable in the full eye assessment consultation and followed the same process as described previously for CICC.

The optometry clients were asked to complete the AUSDRISK in the period before the eye dilating drops took effect. This timing for completing the AUSDRISK was decided as suitable by the optometrists. The optometrists administered the AUSDRISK as part of the full assessment as this gave them the opportunity to discuss the importance of regular screening for any vision changes, which may highlight risks for a number of medical conditions including diabetes/pre-diabetes. Again the clients scoring in the HR range were requested to participate in the follow-up survey. If they agreed the same procedure as described for CICC previously was implemented.

Unfortunately there was a change in ownership of the optometry branches during the course of AUSDRISK data collection, which limited the participation of the practices and health professionals.

There was no further contact with the participants at CICC and optometry practices except for those who had provided signed written consent to participate in the follow-up survey.

Seniors' Card mail-outs

In order to utilize the Seniors' Card mail-out[11], the Manager of the Seniors' Bureau in the Tasmanian Government Department of Premier and Cabinet provided written consent to the AUSDRISK study using 3 mail-outs of the Seniors' Cards to facilitate statewide distribution of the AUSDRISK questionnaires. This requirement was in addition to the ethics approval, which covered all settings. A Tasmanian Government Senior's Card (SC) is available on application to any person aged 60 years or over who is not in more than 20 hours paid employment per week. It is not a pension but is supported by Tasmanian Government and non-Government businesses, which provide a discount for their services or sales on presentation of the SC. Every six to eight weeks, 400-500 new or renewed Senior's Cards are mailed out statewide to eligible older adults in Tasmania. The SC mail-out has been used on occasions for distribution of health promotion material of relevance to older individuals such as information on Falls Prevention.

The AUSDRISK questionnaire and instruction sheet/consent form, and Reply Paid envelope were included with a Senior's Card and an accompanying letter from the Manager of the Seniors' Bureau which included a recommendation for consideration by the recipients to participate in the AUSDRISK study.

There were three mail- outs in 2014 in April, July/August and November which together provided a convenience sample of 1500 older adults from which participants could self-select to participate.

The instruction sheet/consent form provided the eligibility criteria and instructions to complete the AUSDRISK; complete the demographic information (age, gender, familial risk and total points score) on the front of the information sheet; sign the consent form to participate; and if scoring HR and agreeing to participate in a follow-up survey, provide written agreement and preferred contact details and return all in the Reply Paid envelope.

Data entry and analysis

De-identified quantitative data were recorded from the Information/Consent forms and Survey Monkey forms and compiled into Microsoft Excel spreadsheets.

De-identified qualitative data were compiled from paper-based records of interview for the follow-up survey.

De-identified data were also compiled from paper-based records of the participating health professional and administrative staff.

RESULTS

Over a 6 month period (May – November 2014) a total of 1717 adults mean age 64.5 years were offered the opportunity to participate in the AUSDRISK study conducted by the University of Tasmania, School of Medicine. Invitations to participate were sent via three statewide Seniors' Cards mail-outs to 1500 older adults; to a further 177 adults attending a local Community Integrated Care Centre in Southern Tasmania and another 40 adults were invited when they attended two optometry practices in the greater Hobart area.

A total of 401 adults (401/1417; 28.3%) responded to the initial invitation to participate, of whom 65 had diabetes and were ineligible to participate and 27 subsequently chose to withdraw. The total of 309 adults (21.8%) completed the AUSDRISK questionnaire. Of those who were invited to complete the AUSDRISK, 144 individuals (144/1417; 10.16%) scored in the High Risk (HR) range (≥12 points); 152 (152/1417; 10.7%) scored in the Intermediate Risk range (6-11 points) and 12 (12/1417; 0.8%) scored in the Low Risk range (5 points or less) (ref Table 1).

Table 1: Setting x Participation rate x AUSDRISK risk rating

Setting for DM risk assessments	Invitations to participate	Responses to participate in AUSDRISK	Completed AUSDRISK	Low risk Rating (5 points or less)	Inter Risk Rating (6-11 points)	HR Rating (≥ 12 points)
Community ICC N/Ps	177	95 (53.7%)	81 (45.8%)	11/81 (13.0%)	38/81 (46.0%)	32/81 (39.0%)
Optometry ≥50 years	40	27 (67.5%)	26 (65.0%)	1/26 (3.0%)	13/26 (50.0%)	12/26 (46.0%)
S Card mailout 1 ≥60 years	500	64 (16.0%)	52 (10.0%)	0	24/52 (46.0%)	28/52 (54.0%)
S Card mailout 2 ≥60 years	500	116 (23.0%)	77 (15.0%)	0	42/77 (54.0%)	35/77 (46.0%)
S Card mailout 3 ≥60 years	500	113 (28.3%)	72 (14.0%)	0	35/72 (48.0%)	37/72 (52.0%)
TOTAL	**1717**	**401 (23.0%)**	**309 (17.0%)**	**12/217 (5.52%)**	**152/309 (49.0%)**	**144/309 (46.0%)**

Results from Clarence Integrated Care Centre:

A total of 177 new patients were invited to participate in the AUSDRISK study at Clarence Integrated Care Centre. The age range was 28 – 85 years.

Twenty-eight new patients (15.8%) had previously been diagnosed with diabetes (23 Type 2 diabetes; 5 Type 1 diabetes). Fifty–four new patients (30.5%) declined to participate. Ninety-five new patients (53.7%) completed the AUSDRISK, however 14 questionnaires were incomplete and could not be included in the analysis. Thus a total of 81 participants (45.8%) provided AUSDRISK results.

Thirty-two participants scored High Risk (12 points or more); 38 participants scored at Intermediate Risk (6-11 points) and 11 participants scored at Low risk (5 points or less).

High Risk (12 points or more) 32 individuals (age range x – y)

Table2: Results Clarence Integrated Care Centre

Clarence Integrated Care Centre		
AUSDRISK questionnaires	177	
Response rate	95	53.7%
AUSDRISK completion	81	**45.8%**
High Risk % completers	32	**39.0%**
High Risk 1 (12-15 points)	14	
High Risk 2 (16-19 points)	11	
High Risk 3 (20+ points)	7	
Intermediate Risk	38	**46.0%**
Low Risk	11	**13.0%**
Type 2 diabetes	23	13%
Type 1	5	
Total diabetes	28	**15.8%**
Active non-participation	54	
Incomplete responses	14	
Non response rate	68	**38.4%**

Within the High Risk category: 14 participants scored High Risk 1 (12-15 points);

11 participants scored High Risk 2 (16-19 points); and 7 participants scored High Risk 3 (20 points or more). Of the 32 participants who scored in the High Risk range only 10 (12.3%) agreed to complete the follow-up survey. Survey results showed that 7

individuals attended a GP for a blood test and 3 individuals chose not to attend (2xHR1; 1xHR2). Seven HR individuals who attended for a blood test - 6 HR (3xHR3; 2xHR2; 1xHR1) showed normal blood glucose levels. The only HR individual who showed an elevated blood glucose (EBG) level was a female who scored 13 (HR1); aged 75 years and had a family history of diabetes. 12 HR clients had a family history of diabetes but only 5 had blood glucose testing; 4 had normal blood glucose results.

Intermediate Risk (6-11 points): 38 individuals (age range 30 – 84 years).

Under 35 years – 7 females (2 with family history; all had risk factors)

35-44 years – 2 females; 3 males (1 female with family history)

45-54 years – 4 females (1 with family history); 6 males (1 with family history)

55-64 years – 5 females (1 with family history)

65 years and over – 6 females; 5 males .

Low Risk (5 points or less) – 11 (age range 23-40 years)

8 females (2 with family history; 5 with risk factors); 3 males (2 with risk factors)

Family History – In the CICC group, 20/81 participants (25%) reported a Family History of diabetes and additional modifiable Risk factors for type 2 diabetes.

Results from the Optometry practices.

During the period July- August 2014 there were 40 clients who attended the optometry practices for a full eye assessment with dilatation of pupils. Of those, thirteen clients (13) were previously diagnosed with type 2 diabetes and were attending as part of a care plan for diabetes management. Of the remaining clients during this period all agreed to participate.

Optometrists completed 26 AUSDRISK assessments.

Results (Table 3):

- 13 previously diagnosed with type 2 diabetes
- 26 eligible to complete AUSDRISK
- 26 clients completed AUSDRISK
  - 12 clients scored in the High Risk range
  - 13 clients scored in the Intermediate Risk range
  - 1 client scored in the Low Risk range
  - 3 HR clients agreed to follow-up
  - 1 HR client completed the follow-up survey

Table 3. Optometry practice results.

Optometry Practices		
AUSDRISK questionnaires/total clients	40	
Response rate	27	67.0%
AUSDRISK completion	26	**65.0%**
High Risk	12	**46.0%**
High Risk 1 (12-15 points)	9	75.0 %
High Risk 2 (16-19 points)	2	16.0 %
High Risk 3 (20+ points)	1	8.0 %
Intermediate Risk (IR)	13	**50.0 %**
Low Risk (LR)	1	**3.0 %**
Type 2 diabetes	13	**32.5%**
Type 1	0	
Total diabetes	13	
Active non-participation	0	
Incomplete responses	1	2.5%
Non response rate	0	**0**

High Risk

Within the HR group (12 clients), 6 reported a Family History and 10, including those with a Family History had additional multiple modifiable Risk Factors.

Of the HR clients, 9 declined to complete the follow-up survey – HR3 = 1; HR2=1; HR1=7. Three HR clients agreed to follow-up – 2 completed the survey; none completed biomedical assessment. The 6 HR clients with a Family History did not complete the follow-up survey.

Intermediate Risk

Of the 13 Intermediate Risk (IR) clients, 3 reported a Family History including one individual with additional modifiable risk factors. Eight IR clients had modifiable Risk Factors.

Diabetes

The 13 clients diagnosed with type 2 diabetes were attending for a full eye assessment as part of their diabetes management.

Family History:

In the optometry group, 9 clients (22.5%) reported having a Family History and seven of these nine had additional modifiable Risk Factors.

Results from the Seniors' Card mail-outs (table 4)

Approximately 23.0 % of recipients mean age 65.5 years completed and returned the AUSDRISK. Of the responders 24 (10.6%) had diabetes; 101 participants (44.7%) were assessed HR (65 males: 46 females) and 101 were identified as having an Intermediate Risk (IR).

Table 4 Seniors' Card results:

3 Seniors' Card mailouts 2014		
AUSDRISK questionnaires	1500	
Total Response	401	26.0%
AUSDRISK completion	309	20.0%
High Risk	101	32.0%
High Risk 1 (12-15 points)	48	
High Risk 2 (16-19 points)	37	
High Risk 3 (20+ points)	16	
Intermediate Risk	101	32.0%
Low Risk	0	
Type 2 diabetes	23	
Type 1	1	
Total diabetes	24	5.00%
Active non-participation	67	16.0%
Non response rate		74.0%

Follow-up Survey results

Those individuals who scored High Risk on the AUSDRISK were invited to participate in a follow-up survey. Of the 144 HR individuals who completed the AUSDRISK, one hundred and ten provided their preferred contact details – email or phone –to participate in a follow-up survey 6-8 weeks post AUSDRISK completion. Subsequently, when these HR individuals were contacted to complete the survey only 79 HR individuals (thirty-three females and forty-six males) agreed to participate in the survey. Participation in the follow-up survey was not evenly distributed across all settings – 62.4 % SC completed the survey, whereas only 31.3% of those at the Community ICC and 8.3% at Optometry practices completed the survey (ref Table 5).

Table 5: Number of HR participants who completed AUSDRISK x setting x High Risk level x survey completion (%)

SETTINGS	HIGH RISK (12 points or more)			
	HR1 (12-15 points)	HR2 (16–19 points)	HR3 (≥ 20 points)	TOTAL
CICC COMMUNITY CARE SURVEY (S) %	14 S = 4 (1)*	11 S = 3	7 S = 3	**32** **S = 10 (1)* 31.3%**
OPTOMETRY SURVEY %	9 S = 1	2 S = 0	1 S = 0	**12** **S = 1 8.3%**
SENIORS' CARD MAIL-OUT 1 SURVEY %	11 S = 11	8 S = 7(1)*	9 S = 8(2)*	**28** **S = 26 (3)* 93.1%**
SENIORS' CARD MAIL-OUT 2 SURVEY %	20 S = 8	12 S = 7(1)*	3 S = 3	**35** **S = 18 (1)* 51.4%**
SENIORS' CARD MAIL-OUT 3 SURVEY %	16 S =11 (1)*	17 S = 9(1)*	4 S = 4	**37** **S = 24 (2)*64.9%**
TOTAL HR **Survey completion % of total**	**70** **S = 35 (2)*** **50.%**	**50** **S = 26 (3)*** **52.0%**	**24** **S = 18 (2)*** **75.0%**	**144** **S = 79(7)*** **55.2%**

- Number of participants diagnosed with elevated blood glucose (in brackets)

Results from the survey showed that 44 HR participants (53.8%) had attended their GP for biomedical assessment with 43 of the attendees having diagnostic blood tests. Following the blood tests, 36 individuals (85.4%) were advised by their GP that they did not have type 2 diabetes; 7 individuals (14.6 %) had "elevated blood glucose/pre-diabetes". No HR participants who had blood tests were diagnosed with diabetes. Approximately 50 percent of those who completed the follow-up survey but had not

attended for biomedical assessment stated they planned to request blood tests when they had their regular annual or bi-annual appointment with their GP. However the remainder indicated they would not be attending for biomedical assessment.

Within the High Risk range (≥ 12 points) there are three categories reflecting increasing risk of developing Type 2 diabetes - HR1 =12-15 points (approximately 1 in 14 will develop diabetes); HR2 = 16-19 points (approximately 1 in 7 will develop diabetes) and HR3 = 20 points or more where the risk is that 1 person in every 3 will develop diabetes. There was no association between the levels of High Risk and pre-diabetes (elevated blood glucose) and no association between the settings and elevated blood glucose (Table 6).

Table 6: HR survey completers x setting x HR category x glycaemic status (elevated blood glucose (EBG): normal blood glucose (NBG)) x percentage

HR category x survey completers	CICC		OPTOM		Senior's Card		Percentage (%) EBG/Normal Glucose level			
Glycaemic status	*EBG*	*NBG*	*EBG*	*NBG*	*EBG*	*NBG*	*EBG*	*NBG*	*% EBG*	*% NBG*
HR1 = 34	*1*	*3*	*0*	*1*	*1*	*29*	*2*	*33*	*5.71%*	*94.28%*
HR2 =	*0*	*3*	*0*	*0*	*3*	*20*	*3*	*23*	*11.53%*	*88.46%*
HR3	*0*	*3*	*O*	*0*	*2*	*13*	*2*	*16*	*11.11%*	*88.88%*
Total	*1*	*9*	*0*	*1*	*6*	*62*	*7*	*72*	*8.86%*	*91.13%*

Of those diagnosed with elevated blood glucose or “pre-diabetes”, two participants (one male: one female) were in category HR1; three participants (2 male: 1 female) were in HR2 and two participants (2 females) were in HR3. One participant with elevated blood glucose was a patient of the Community Integrated Care Centre and the other six were from the Seniors’ Card mail-out groups There was no association between risk score and family history or age or gender (Table 4).

Table 7: Participants: rated High Risk on AUSDRISK; diagnosed elevated blood glucose on biomedical assessment

Setting	Age	Risk score	Gender	Family History
CICC	75 years	13	Female	Yes
Seniors’ Card	63 years	13	Male	No
Seniors’ Card	67 years	16	Male	Yes
Seniors’ Card	76 years	17	Male	No
Seniors’ Card	60 years	18	Female	No
Seniors’ Card	60 years	21	Female	No
Seniors’ Card	70 years	23	Female	No

Overall the rate of attendance to non-attendance for biomedical assessment increased as the level of High Risk increased from HR1 to HR2 and HR3. However this pattern was not reflected across both genders. There was a noticeable interaction between gender, risk level and attendance or non-attendance. The male response pattern of attending or not attending for biomedical assessment showed that as the level of risk increased, the level of GP attendance decreased. Whereas the female response rate pattern of attending to not attending increased uniformly as the levels within high risk increased, with 100 % attendance at HR3 (Table 8).

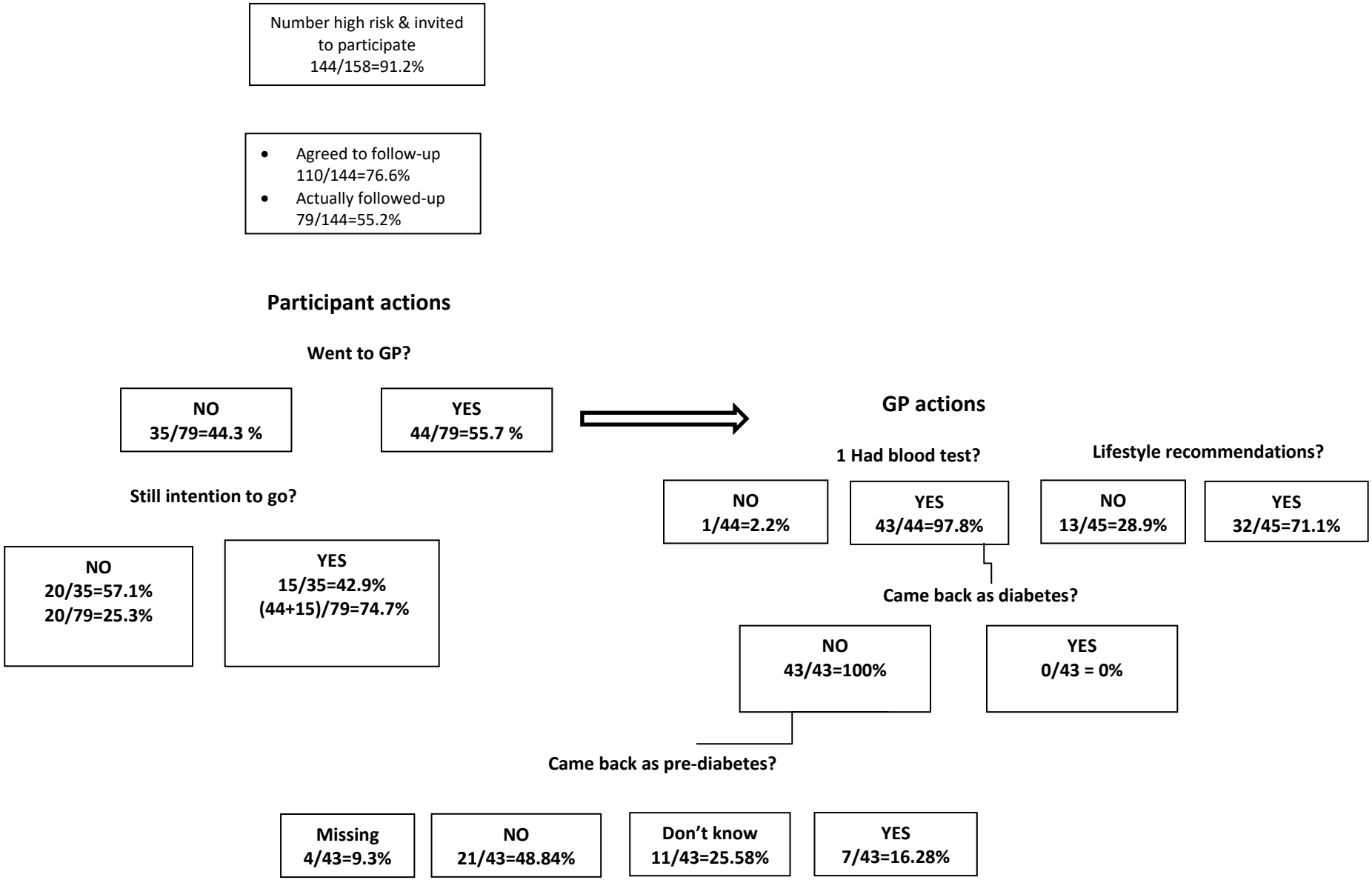
Table 8: Gender HR survey responders x GP attendance/non-attendance x HR risk level

HR participants in follow-up survey	46 HR Male		33 HR Female		80 HR (male + female)	
Attendance vs non-attendance to GP for biomedical assessment	Attend GP	Non-attend GP	Attend GP	Non-attend GP	**Attend GP**	**Non-attend GP**
HR1 = 35	11	9	8	7	**19** **54.3%**	**16** **45.7%**
HR2 = 26	8	7	8	3	**16** **61.5%**	**10** **38.5%**
HR3 = 18	4	7	7	0	**11** **61.1%**	**7** **38.9%**
Total HR1/2/3 = 79	23	23	23	10	**46** **56.3%**	**33** **43.7%**
Percentage attendance/nonattendance x gender	**50.0%**	**50.0%**	**69.7%**	**30.3%**	**56.3%**	**43.7%**

Results

Analysis of AUSDRISK results

Flowchart


Number high risk & invited to participate 144/158=91.2%
Agreed to follow-up 110/144=76.6%
Actually followed-up 79/144=55.2%
Participant actions
Went to GP?
NO 35/79=44.3 %
YES 44/79=55.7 %
Still intention to go?
NO 20/35=57.1% 20/79=25.3%
YES 15/35=42.9% (44+15)/79=74.7%
GP actions
1 Had blood test?
NO 1/44=2.2%
YES 43/44=97.8%
Lifestyle recommendations?
NO 13/45=28.9%
YES 32/45=71.1%
Came back as diabetes?
NO 43/43=100%
YES 0/43 = 0%
Came back as pre-diabetes?
Missing 4/43=9.3%
NO 21/43=48.84%
Don't know 11/43=25.58%
YES 7/43=16.28%

Flowchart interpretations

Participant actions

- 55.7%(44/79) had attended their GP
- 44% (35/79) did not see their GP.
    - Of those who didn't see their GP, 54% (19/35) (or 24% (19/79) of the total)) did not have the intention of seeing their GP.
- So half had acted on seeing a GP, another quarter still had the intention to go, while the last quarter did not have the intention to go at all.

GP actions

44 participants presented to their GP

- In 98% (43/44) of the instances, the GP acted by ordering a blood test
- In 73% (33/44) of the instances, the GP discussed lifestyle changes
- Of those who received a blood test, 70% also received lifestyle advice
- The person who did not receive a blood test, did receive lifestyle change advice

Differences in the follow-up survey participants

Compared to those who did not participate, those who participated in the follow up were:

- 3.36 years older (p=0.057)
- More often males (p=0.04)
- Had a similar diabetes risk score (p=0.40)
- Were more likely to have a family history of diabetes but this difference was not significant (p=0.07)
- Very different in type/setting (p<0.01): Most likely to be Senior Card participants and least likely to be Optometry participants Differences by GP attendance
- No significant difference by age (p=0.81)
- No significant difference by gender (p=0.19)
- No significant difference by risk score (p=0.46)
- People with a family history were more likely to attend a GP, but this difference was not significant (p=0.09).
- No significant difference by GP type/setting (p=0.35)

Interaction effect of gender by GP attendance

- The difference in pattern of attendance at GP between males and females was statistically significant (p=0.01)
- Males with increasing risk score were less likely to see their GP (test for trend p=0.37)
- Females with increasing risk score were more likely to see their GP (test for trend p=0.002)

No association between the risk score and pre-diabetes.

- Compared to those who did not have pre-diabetes, those who did not know whether they had pre-diabetes/high blood sugar had a risk score that was on average 0.94 units higher (p=0.50).
- Compared to those who did not have pre-diabetes, those who had pre-diabetes/high blood sugar had a risk score that was on average 0.95 units higher (p=0.50).

No association between gender and pre-diabetes.

- Compared to those who did not have pre-diabetes, those who did not know whether they had pre-diabetes/high blood sugar were more likely to be female but this was not significant (p=0.10).
- Compared to those who did not have pre-diabetes, those who had pre-diabetes/high blood sugar were more likely to be female but this was not significant (p=0.26).

No association between the type/setting and risk score (continuous measure) (p=0.13, p=32) or between type/setting and risk score category (p=0.37)

Effectiveness of the screening among those who had a blood test done

Of the 44 blood tests, none came back as diabetes

Positive predictive value=

False discovery rate=

	Diabetes	**No diabetes**	Had blood test
Screen showed high risk	0	43 False positive Type 1 error	43
Screen showed not high risk	False negative Type 2 error	True negative	

Survey results of participant beliefs and attitudes

Most survey respondents were unaware of the AUSDRISK questionnaire and its role as a pre-screening tool for assessing diabetes risk. Apart from those participants who had a

family history of diabetes, there were few participants who had an informed understanding of type 2 diabetes, diabetes risk factors, continuum of risk and the benefits of having normal blood glucose levels. The majority of participants did not know that increasing age was a risk factor for type 2 diabetes. Their overall attitude towards Type 2 diabetes was one of being risk averse on multiple levels – concern that increasing age was a risk factor and was not modifiable; fear of complications; concern of individual blame for having diabetes or being at risk, concern that they would have to make significant changes to their lifestyle and ambivalent, in that they were not sure how this could be done or how type 2 diabetes could be effectively managed. The HR individuals who had a normal blood glucose result were relieved, and believed that this result gave them protection from developing type 2 diabetes. They were unaware that their HR status was ongoing.

DISCUSSION

Preamble

To our knowledge the AUSDRISK questionnaire developed in 2008 has not been used in Australia in a systematic manner to identify older people with undiagnosed type 2 diabetes or at high risk for developing this condition and follow them through to biomedical assessment. The prevalence for type 2 diabetes is known to be high (17-20%) in this age group both in Tasmania and nationally, considered to be due to increasing age and rising rates of obesity. Potentially the effect of other chronic conditions associated with ageing and lifestyle restrictions add to the risk factor burden, for example, arthritis and osteoporosis which may lead to reduced physical activity and reduced exercise tolerance, increased sedentary behavior, and overweight/obesity all of which are considered to increase the risk for type 2 diabetes.

We had three main objectives in this study. First, to determine the feasibility and acceptability of utilising the AUSDRISK in healthcare and non-healthcare settings to identify older individuals at High Risk for developing diabetes. Secondly, determine the uptake and effectiveness of the AUSDRISK by following-up those assessed as being at High Risk, to determine their follow-up actions, and those of their General Practitioners, to the older individual being advised to seek biomedical assessment of their glycaemic status. Finally, to examine the knowledge and beliefs about Type 2 diabetes, held by those just recently assessed as High Risk for this condition.

This study achieved its first aim by finding that implementing the AUSDRISK questionnaire was a feasible process face-to-face as part of routine patient health assessments in both the

public and private health sectors and for the first time it showed that a routine, well established non-healthcare mail-out could be effectively utilized to provide a low cost means for state-wide distribution of the AUSDRISK to the older population in Tasmania, which would potentially include those people not currently interacting with the healthcare system.

The second aim to determine the follow-up actions of HR participants and their GPs found that of the 79 individuals who completed the follow-up survey only 44 HR individuals attended their GP for a biomedical assessment. When this result was considered in the light of the 144 individuals who scored High Risk, it showed that only one-third of those individuals who scored High Risk attended their GP for a biomedical assessment. This response pattern clearly indicates that distributing an AUSDRISK questionnaire does not facilitate recipients to seek further clarification of their diabetes risk status.

General Practitioners responded as recommended by *NHMRC Guidelines for the Prevention and Management of Type 2 diabetes (2009)* by ordering blood glucose tests, and providing lifestyle modification recommendations to the majority of those who attended. GPs also indicated that they would continue to monitor those participants who had been diagnosed with an elevated blood glucose level. Thus, a regular management program for a previously unrecognized risk condition for developing type 2 diabetes was established.

The final aim to examine the knowledge and beliefs about Type 2 diabetes, held by those just recently assessed as High Risk for this condition revealed that older people generally have a risk averse and ambivalent attitude towards type 2 diabetes, its management and its potential severe complications. They had little or no knowledge and understanding of diabetes risk nor the potential for its effective management.

Type 2 Diabetes Risk Status

The diabetes risk level status (Intermediate or High) of older adults was identified in both non-medical healthcare settings and via the non-healthcare mail-outs. Results indicated that 36 of the survey respondents (83 %) who had registered as High Risk on the AUSDRISK were found to be normo-glycaemic on biomedical assessment. Seven participants assessed as High Risk were advised they had elevated blood glucose. No participant was diagnosed with type 2 diabetes. These results raised the question of the discriminative ability of the AUSDRISK questionnaire when implemented in a limited age range cohort (only those over 50 years). Whilst the age range limitation may have had an impact on the current study, the poor initial and follow-up response rates would likely also be contributing factors.

The fact that no individuals were diagnosed with diabetes might suggest that within the cohort tested there were more participants in the HR1 and HR2 categories and this was the case (35 HR1:26 HR2:18 HR3). However diagnosed elevated blood glucose/pre-diabetes was identified at all HR levels not just HR3 and not all those identified as HR3 were identified with elevated blood glucose. The results were found to have no predictive value for type 2 diabetes or elevated blood glucose.

Response Rates

In all settings (health and non-health), the limited response rate of older adults to the initial introduction of the AUSDRISK questionnaire suggested that the questionnaire and its role in assessing diabetes risk prior to diagnostic testing was not well known or understood. The initial uptake of the AUSDRISK, from a distribution of 1717 questionnaires was only 401 responses (23.4 %), and of those, 309 individuals (18.0 %) were eligible to participate.

The limited initial and subsequent participation rates to determine participants' diabetes risk status reflected findings in other national and international screening studies. The ADDITION Diabetes study in the United Kingdom (2012)[12] found that mail-out questionnaires yielded a relatively poor rate compared with the national diabetes risk screening program conducted on a regular basis within GP practices. That no HR participants were diagnosed with diabetes may be due to the limited age range of the participants and the small size of the final cohort of 44 individuals (44/79; 44/144) who completed the AUSDRISK, the follow-up survey and were bio-medically assessed. It may also reflect self-selection not to participate. According to the Theory of Planned Behaviour[13] those adults who perceived high personal risk associated with the AUSDRISK questionnaire would likely either not participate at all, or if initially participating, would not proceed to a biomedical assessment with a GP.

Although the follow-up survey in this study was completed by a small number of participants, the negative attitudes and beliefs in relation to type 2 diabetes were consistent and clearly identified those issues that would need to be addressed to improve the uptake and full participation rate for this age cohort[14,].

Follow-up Survey

A total of 79 participants completed the follow-up survey- 33 female and 46 male. Distribution across the risk levels showed 35 HR1 (17 female: 18 male); 26 HR2 (10 female: 16 male) and 18 HR3 (7 female: 11 male). This numerical pattern of HR levels reflected those of the larger group of 145 AUSDRISK HR participants (numbers of participants in HR levels HR1>HR2>HR3). Forty-four HR individuals (21 female: 23 male) completed the survey, and attended the GP for biomedical assessment and 35 (12 female: 23 male) did not. Thus slightly over half (56.3 cent) of those HR individuals who scored HR and completed the

survey took action to seek a biomedical assessment of their diabetes assessment. Whilst more males than females completed the survey (46 males: 33 females), females were more likely to follow up by attending their GP (64.7%) whereas there was only a 50:50 chance that males would see their GP. Survey results showed there was an increase in rate of attendance to non-attendance for biomedical assessment as the level of High Risk increased from HR1 to HR2 and HR3. However this pattern was not reflected across both genders. There was a significant interaction between gender, risk level and attendance or non-attendance. The male response pattern of attending or not attending for biomedical assessment showed an approximate 50:50 not attend/attend across all levels but at HR3 the level of attendance decreased further. Whereas the female response pattern of attending or not attending increased uniformly with the increasing level of high risk, with 100 % attendance at HR3. This male response pattern has been well-recognized in other chronic condition screening and clinical settings. As men have a higher prevalence of type 2 diabetes, the male response pattern of reduced engagement with increased personal health risk would be a challenge to address for any diabetes screening program.

General Practitioner response

The response of general practitioners to the High Risk score of their patients showed that GPs were following the *Guidelines*[5] with 43 of the 44 HR individuals receiving blood glucose testing. The GPs also indicated the importance of lifestyle modification. However lifestyle modification information was not universally provided as only 33 of the 44 HR individuals who had a biomedical assessment received this recommendation. This lack of or limited reinforcement on the part of GPs, of the importance and benefit of lifestyle changes, may inadvertently reduce an individual's perception of their diabetes risk. Those individuals who

did not receive lifestyle advice included 3 HR2 and 1 HR3. GPs appeared to be responding to the current normo-glycaemic status of the patient rather than their ongoing High Risk status.

Participant Knowledge

Participants assessed as being at High Risk appeared to have no understanding of the concept of ongoing diabetes/pre-diabetes risk, nor the continuum of risk and, that they would remain at high risk despite being normo-glycaemic at time of testing. Those individuals who were bio-medically assessed as not having type 2 diabetes felt "relieved" and considered that this result gave them some form of protection from ever developing diabetes. They were somewhat confused that they had scored High Risk on the AUSDRISK but that they didn't have diabetes nor pre-diabetes when their blood glucose was tested. Many of the HR participants who completed the AUSDRISK also felt disempowered to make a change to their situation when age alone was a major risk factor component that was non-modifiable[15,16,17,18].

This lack of knowledge about diabetes and diabetes risk and fearful attitude towards type 2 diabetes would need to be addressed/overcome as part of and prior to, implementing a systematic diabetes risk screening process for older adults. From a health benefit viewpoint it is difficult to promote the concept of risk over an extended period, which may be perceived by some to be longer than their expected lifespan. There was no understanding of the immediate benefits of having a blood glucose level within the normal range.

For the first time in history people in the older age group are living longer than any previous generation, screening and assessment offers an opportunity to promote the immediate benefits to their quality of life and facilitate their independence from having normal blood glucose levels.

Validity of the AUSDRISK Questionnaire

Although the AUSDRISK can be implemented via all settings studied, on biomedical testing no HR individuals were found to have diabetes. The AUSDRISK scores of those diagnosed with elevated blood glucose was spread across all HR categories rather than in the highest HR score. Both findings suggest a lack of discriminative capacity in the AUSDRISK. The results of our study would lend support to earlier studies[8,19] which found that most basic diabetes screening questionnaires can identify people at high risk of developing diabetes in a 5-10 year time frame, but at the time of implementation most screening questionnaires over-estimate the actual risk of diabetes.

In a post hoc analysis we reviewed our results against the Finnish Diabetes Risk Score (FINDRISC)[20], (validated within a comparable population to the AUSDRISK) and on which the concept of the AUSDRISK was based. We found that in particular, the scoring for "age" and "gender" in the AUSDRISK could account for 4-7 points in excess of those allocated in the FINDRISC. Thus in our study, a number of participants classified HR on the AUSDRISK would have scored in the Intermediate Risk range of the FINDRISC or at a lower classification in the High Risk range. These findings and the lack of discriminatory ability of the AUSDRISK in an older age cohort needs further investigation.

CONCLUSION

Whilst this study found that the AUSDRISK could be implemented in settings other than medical and in so doing would increase the potential access to the older population, this study identified individual and systems barriers, which would need to be addressed for AUSDRISK screening to be implemented effectively. The validity of AUSDRISK for use as a screening tool for assessing diabetes risk in an older age group is a priority for further investigation. Whilst addressing the issues identified in this study, other diabetes screening

methods such as point-of-care testing with HbA1c warrant consideration for the older age cohort, with reference to advantages/disadvantages for participants, health professionals, settings, cost and impact as a way forward for determining effective identification of diabetes risk in the older age group.

This study found that including the AUSDRISK in regular healthcare settings and in a non-health-related mail-outs was feasible and low cost for inviting older adults to assess their diabetes risk. However completion of the AUSDRISK, whilst identifying those at HR, was not perceived by participants as being reflective of current and/or future diabetes risk, and for the most part did not promote most HR participants to seek biomedical assessment. Pre-screening education is clearly required for older people to reduce their aversion and ambivalence to type 2 diabetes prevention and management and facilitate informed choice towards diabetes/pre-diabetes screening.

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Appendix 9

Doctor of Health Research Seminar 22.9.2016

SCREENING FOR TYPE 2 DIABETES IN 'YOUNG-OLD' INDIVIDUALS

1

Screening for type 2 diabetes in *young-old* individuals

- Individuals in older age group living longer than any previous generation
- *Young old* individuals have 15-25 years life expectancy
- Healthcare emphasis - ensure good quality of life and effectively manage age-related health risks
- High prevalence of T2D in older age – 16-20%
- No symptoms for T2D to alert individuals of their risk

2

Screening for type 2 diabetes in young-old individuals

- NHMRC Guidelines recommend 3-step screening process for case finding T2D

1. Complete AUSDRISK to identify High Risk (HR)
2. If HR – biomedical assessment for glycaemic status
3. Biomedical assessment – HbA1c or FPG
4. Confirmation glycaemic status - OGTT

3

Screening for type 2 diabetes in young-old individuals Is

- No national population screening program (for any age group) in Australia for identifying individuals with or at High Risk for developing type 2 diabetes.
- Opportunistic screening for via GP presentation – usually for an unrelated condition
- AUSDRISK rarely used by GPs as entry step for screening
- Individuals with unrecognised/untreated T2D or elevated blood glucose have increased risk for CVD, cancer and dementia

4

Aims of this study

- To determine the feasibility of using real world scenarios to implement AUSDRISK as entry step to community based screening for T2D in young-old (60-74 years) adults in Tasmania.
- To evaluate effectiveness of AUSDRISK in finding those at High Risk (HR) for T2D and undiagnosed T2D.

5

Screening for type 2 diabetes in young-old individuals

- Two non-medical community distribution methods for AUSDRISK
- Direct approach at public and private community – based health services (integrated care centre, 2 optometry practices)
- Indirect approach via an established *Seniors' Card* mailout system
- Invitation to complete AUSDRISK and follow instructions for assessed level of risk

6

Results

- 308 (18.7%)respondents
- 136 HR(43.8%); 152 IR (49.4%); 12 LR (3.9%)
- HR – complete survey to document actions towards completing biomedical assessment = 92 (67.6%)
- HR - Attend GP for biomedical assessment = 50 (54.3%)
- HR - Plan to attend GP = 18 (19.6%)
- HR - No intention to attend GP = 24 (26.1%)

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Biomedical assessment results following AUSDRISK

- No biomedically-assessed older HR individuals had undiagnosed T2D
- 14.3% HR – undiagnosed elevated blood glucose (EBG)
- 85.7% - normal blood glucose levels (NBG)
- Those bio-medically assessed as having EBG had a risk score that was on average 0.95 units higher (p=0.50) than those assessed as NBG.

8

Australian studies using AUSDRISK

- Results of AUSDRISK assessment for non-diabetes participants (50 - 75 years) in other Australian T2D prevention studies
  - 84.8% HR – normoglycaemic
  - 15.2% HR – elevated blood glucose
    - Melbourne Diabetes Prevention Study
    - Greater Green Triangle study

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Screening for type 2 diabetes in young-old individuals

- Purpose of a Risk Assessment screening test is to identify as many individuals who require further testing because they may have T2D, and identify those for whom the diagnosis of T2D is unlikely.
- HR AUSDRISK scores had zero positive predictive value for T2D and no association between HR scores and elevated blood glucose result on biomedical testing.

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Additional findings

- Older age individuals unaware of AUSDRISK
- Aware of potentially modifiable lifestyle risk factors – overweight /obese, poor nutrition, insufficient physical activity for health benefit
- Unaware that increasing age is a major non-modifiable risk factor for elevated blood glucose and T2D

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Additional findings

- GP responses
  - Biomedical assessment HR individuals
  - Lifestyle advice for risk reduction
  - Regular 1-3 year testing for EBG
  - No mention of repeat testing for HR individuals currently normoglycaemic
  - No mention of ongoing risk due to age

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Additional findings

- Proportions of HR individuals attending for biomedical assessment increased as the level of risk increased from HR1 – HR3
- Gender based differences in GP attendance – HR males with increasing level of risk less likely to attend GP; HR females more likely to attend GP

13

Additional findings

- Direct invitation response (60%)
- Indirect invitation response (13.7%)
- HR direct invitation to biomedical assessment (12.1%)
- HR indirect invitation to biomedical assessment (53.1%)
- No difference in outcomes of presentation methodology
- Mailout appears to have greater potential for achieving increased participation

14

Screening for type 2 diabetes in young-old individuals

Limitation of study

- Small number of individuals who chose to participate followed by further reduction of participants who completed biomedical assessment.

Strengths

- Real world setting that highlighted implementation issues and negative participant perceptions which would need to be addressed
- Our results comparable to other studies using AUSDRISK

Difficulties

- The politics of AUSDRISK

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Conclusion

- In light of our findings and findings of international studies, further research is warranted in young-old age cohorts to determine the suitability or otherwise of initially using a risk factor questionnaire generally, and AUSDRISK in particular, to identify HR for pre-DM/T2D in a known HR group, prior to implementing a systems approach of 5-yearly biomedical assessment for preDM/T2D in *young-old* individuals.

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Appendix 10 Screening costs

The costs for the *AUSDRISK* questionnaires and the Instruction sheet/Consent form were the same for both the direct (healthcare-related) and indirect (mail-out) recruitment. The *AUSDRISK* tool is supplied free and free of delivery charges from the National Mailing and Marketing Centre (health@nationalmailing.com.au). In total, 2000 x Instruction sheet/consent forms and 1500 Reply-paid envelopes cost $1,871.19.

In addition, the cost of the three mail-outs was $3,045.19 for contracted mailing services.

The costs for direct recruitment by healthcare staff was estimated (15 minutes per patient and 3 hours staff training and support per setting) and were covered within usual services in the healthcare centre and optometry practices.

The cost for biomedical assessment, comprising GP consultation and pathology tests, was covered in full, or part, by *Medicare (*Australian Government Health Services).

At the time of this study, many older persons were “bulk-billed” for short GP consultations. Similarly, the pathology tests were “bulk-billed”. The term bulk-billing refers to the services being paid a standard fee under the Australian Government Health Services *Medicare* with the patient having no out-of-pocket expenses. This cost arrangement is no longer current.

In November 2014 (after this study had been completed), *Medicare* introduced a new pathology item for the use of the HbA1c test for diagnosis of T2DM (MBS* item 66841), which may be requested by the GP for diagnostic purposes of T2DM for asymptomatic at-risk patients, once every 12 months. This annual test is free for those patients who fulfil the following criteria. These are patients with either (i) a medical condition or ethnic background associated with high rates of type 2 diabetes, or (ii) an Australian type 2 diabetes risk (*AUSDRISK*) score of 12 points or greater, placing them at increased risk of diabetes – (Reimbursed by Medicare).